NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE

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I hereby declare that the thesis entitled "**NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE**" submitted towards partial fulfillment of the requirements for the award of **DM in Gastroenterology** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Ajit Sood**, Professor & Head, Department of Gastroenterology and **Dr. Ramit Mahajan**, Associate Professor, Department of Gastroenterology. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Family

&

Teachers

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ASPEN	American Society for Parenteral and Enteral Nutrition
BIA	Bioelectrical Impedence Analysis
BMI	Body Mass Index
CD	Crohn's Disease
CT	Computerized Tomography
DEXA	Dual-Energy X-ray Absorptiometry
HCP	Health Care Practitioner
IBD	Inflammatory Bowel Disease
MAC	Mid Arm Circumference
MNA - SF	Mini Nutritional Assessment-Short Form
MIRT	Malnutrition Inflammation Risk Tool
MRI	Magnetic Resonance Imaging
MUST	Malnutrition Universal Screening Tool
NRI	Nutritional Risk Index
NRS	Nutrition Risk Screening
NRS -2002	Nutrition Risk Screening 2002
NST	Nutrition Screening Tool
SD	Standard Deviation
SGA	Subjective Global Assessment

SMI	Skeletal Muscle Index
TSFT	Triceps Skinfold Thickness
UC	Ulcerative Colitis

ABSTRACT

Introduction: Nutrition disturbances are frequent in IBD patients and are associated with poor clinical outcomes. The severity of malnutrition in IBD is dependent on activity, duration and extent of the disease. Early implementation of nutritional screening tools followed by a comprehensive nutritional assessment is the first step to reduce the prevalence of malnutrition and improve clinical outcomes.

Aim: To study the nutritional status in patients with Inflammatory Bowel Disease and study the correlation of nutritional status with disease course and complications.

Materials and methods: This study was conducted among 125 outpatients with Inflammatory Bowel Disease at Department of Gastroenterology, DMCH, Ludhiana from April 2020 to August 2021 with follow up period of 1 year. Various NSTs & NATs were used for nutritional assessment of IBD patients. Nutritional status of patients with disease in remission & active disease was assessed and compared. Nutritional tools were compared with disease outcomes.

Results: Mean age of patients was 40.27±13.23 years. Ratio of UC to CD patients was 4.2:1. Mean values of MIRT, MUST, SaskIBD, BMI & Mid Arm Circumference were significantly low in patients with active disease at enrollment. Nutritional screening with MIRT, MUST & SaskIBD showed malnutrition risk in 9.6%, 48% & 45.6% of patients respectively. During follow up, relapse was seen in 18.18% patients who were initially in remission.

Conclusion: Risk of malnutrition is high in patients with IBD using different nutritional screening tools. Patients with active disease have more severe nutritional abnormalities that those with disease in remission. MUST, SaskIBD & albumin levels were found to predict clinical outcome in IBD patients.

Keywords: IBD: Inflammatory Bowel Disease, MIRT: Malnutrition Inflammation Risk Tool, MUST: Malnutrition Universal Screening Tool, SaskIBD: Saskatchewan Inflammatory Bowel Disease: NST: Nutrition Screening Tool, NAT: Nutrition Assessment Tool

TABLE OF CONTENTS

S. NO.	TOPIC	PAGES
I	INTRODUCTION	1-2
II	AIMS AND OBJECTIVES	3
III	REVIEW OF LITERATURE	4-20
IV	MATERIALS AND METHODS	21-27
V	OBSERVATIONS AND RESULTS	28-69
VI	DISCUSSION	70-78
VIII	SUMMARY AND CONCLUSIONS	79-81
	BIBLIOGRAPHY	82-91
	APPENDICES – I - PROFORMA - MASTER CHART	
	APPENDICES – II - APPROVAL LETTER OF THESIS PLAN - THESIS PLAN	

LIST OF TABLES

TABLE NO.	TITLE	PAGE NO.
1	AGE DISTRIBUTION OF PATIENTS	29
2	SEX DISTRIBUTION OF PATIENTS	30
3	DISTRIBUTION ACCORDING TO IBD TYPE	31
4A	CROHN'S DISEASE SEVERITY AT BASELINE	32
4B	ULCERATIVE COLITIS DISEASE SEVERITY AT BASELINE	33
5	DISEASE EXTENT AT BASELINE	34
6	COMORBIDITIES	36
7	MEDICATIONS AT BASELINE	37
8	DURATION OF DISEASE	38
9	BMI AT BASELINE	39
10	COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN GROUP A & GROUP B	40
11	COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN UC & CD PATIENTS	42
12A	COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN UC PATIENTS IN BOTH GROUPS	44
12B	COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN CD PATIENTS IN BOTH GROUPS	46
13	COMPARING DURATION OF DISEASE WITH NUTRITION PARAMETERS	48
14	NUTRITION RISK SCREENING TOOLS AT BASELINE	51
15A	COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	54
15B	COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	56
15C	COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	57

15D	COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	58
15E	COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	59
15F	COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	60
16A	COMPARISON OF BASELINE PARAMETERS OF THOSE WHO REMAINED IN REMISSION VERSUS THOSE WHO RELAPSED ON FOLLOW UP IN GROUP A	63
16B	COMPARISON OF BASELINE PARAMETERS OF THOSE WHO ACHIEVED REMISSION VERSUS THOSE WHO REMAINED ACTIVE OR RELAPSED ON FOLLOW UP IN GROUP B	65
17A	IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP A	67
17B	IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP B	69

LIST OF FIGURES

FIG. NO.	TITLE	PAGE NO.
1.	PATHOGENESIS OF MALNUTRITION IN IBD	5
2.	PROPOSED APPROACH TO NUTRITIONAL STATUS IN IBD	8
3.	TOTAL MAYO SCORE	23
4.	CROHN'S DISEASE ACTIVITY INDEX	24
5.	MALNUTRITION INFLAMMATION RISK TOOL (MIRT)	25
6.	MALNUTRITION UNIVERSAL SCREENING TOOL (MUST)	26
7.	SASKATCHEWAN IBD (SASKIBD)	26
8.	AGE DISTRIBUTION OF PATIENTS	29
9.	SEX DISTRIBUTION OF PATIENTS	30
10.	DISTRIBUTION ACCORDING TO IBD TYPE	31
11.	CROHN'S DISEASE SEVERITY AT BASELINE	32
12.	ULCERATIVE COLITIS DISEASE SEVERITY AT BASELINE	33
13.	EXTENT OF UC	35
14.	EXTENT OF CD	35
15.	COMORBIDITIES	36
16.	DURATION OF DISEASE	38
17.	BMI AT BASELINE	39
18.	COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN GROUP A & GROUP B	41
19.	COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN UC & CD PATIENTS	43
20.	COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN UC PATIENTS IN BOTH GROUPS	45
21.	COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN CD PATIENTS IN BOTH GROUPS	47

22.	COMPARING DURATION OF DISEASE WITH NUTRITION PARAMETERS	49
23.	MIRT SCORE AT BASELINE	52
24.	MUST SCORE AT BASELINE	52
25.	SASKIBD SCORE AT BASELINE	53
26.	COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	55
27.	COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	56
28.	COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	57
29.	COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	58
30.	COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A	59
31.	COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B	60
32.	OUTCOMES DURING FOLLOW UP	62
33.	COMPARISON OF BASELINE PARAMETERS OF THOSE WHO REMAINED IN REMISSION VERSUS THOSE WHO RELAPSED ON FOLLOW UP IN GROUP A	64
34.	COMPARISON OF BASELINE PARAMETERS OF THOSE WHO ACHIEVED REMISSION VERSUS THOSE WHO REMAINED ACTIVE OR RELAPSED ON FOLLOW UP IN GROUP B	65
35.	IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP A	67
36.	IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP B	69

INTRODUCTION

Inflammatory Bowel Disease (IBD) is a chronic, relapsing, inflammatory disorder of the digestive tract that characteristically develop in adolescence and early adulthood. Nutrition disturbances are frequent in IBD patients and are associated with poor clinical outcomes. The mechanisms underlying malnutrition in inflammatory bowel disease include reduced oral food intake, malabsorption of nutrients, enteric nutrient loss, increased energy requirements due to systemic inflammation and iatrogenic factors like surgery, drugs etc.

The severity of malnutrition in IBD patients is dependent on the activity, duration and extent of the disease and on the magnitude of the inflammatory systemic response. The reported rates of malnutrition in outpatient IBD clinics vary on how malnutrition is defined and measured. The prevalence of malnutrition in inflammatory bowel disease (IBD) patients ranges between 20% and 85%[1]. The prevalence of protein–energy and specific nutrient malnutrition is higher in CD (Crohn's Disease) compared to UC (Ulcerative Colitis) possibly because CD can affect any part of the gastrointestinal tract especially the small bowel.

The evaluation of malnutrition in patients with IBD involves two aspects: nutritional screening and nutritional assessment. Nutritional risk screening (NRS) is a process to predict those at risk of malnutrition so that they can be referred to a registered dietitian for detailed nutritional assessment and intervention. Nutritional assessment is a more complex process generally applied to at risk patients to define their true nutritional status.

Nutritional screening involves a detailed clinical history and use of nutritional screening tools (NSTs).Nutrition screening tools (NSTs) include the malnutrition universal screening tool (MUST), malnutrition inflammation research tool (MIRT), nutrition risk screening (NRS 2002), SaskIBD (Saskatchewan Inflammatory Bowel Disease),nutritional risk

index (NRI), Mini Nutritional Assessment-Short Form (MNA-SF). These are rapid evaluations that can be completed by any member of the medical team.

Nutritional assessment is detailed evaluation of patients for confirmation of malnutrition, characterize the nutritional deficiencies, determine the severity of malnutrition and develop an appropriate treatment. Nutritional assessment includes patient history, food and nutrition related history (e.g. dietary history), anthropometric measurements (Body Weight, Height, BMI, Skinfold Thickness, Mid Upper Arm Circumference, Mid Upper Arm Muscle Circumference), physical examination and assessment including SGA (Subjective Global Assessment), body composition analysis [bydual-energy X-ray absorptiometry (DXA), magnetic resonance imaging (MRI), bioelectrical impedance analysis (BIA), ultrasound, computed tomography (CT)], sarcopenia assessment (skeletal muscle mass and hand grip strength) and biochemical data and disease specific tests. Nutrition assessment tools are more detailed and require greater specialized resources.

Early implementation of nutritional screening tools followed by a comprehensive nutritional assessment in at-risk patients is the first step to reduce the prevalence of malnutrition and improve clinical outcomes in the patients with IBD. The assessment of the nutritional status and the need of supportive nutritional therapy play a pivotal role in the clinical care of inflammatory bowel disease patients. This study intends to assess the nutritional status of patients of IBD using the NSTs and NATs and study the correlation of nutritional status with disease course and complications.

AIMS AND OBJECTIVES

1. To study the nutritional status in patients with Inflammatory Bowel Disease
2. To study the correlation of nutritional status with disease course and complications.

REVIEW OF LITERATURE

The European Society for Clinical Nutrition and Metabolism defines malnutrition as a state resulting from lack of intake or uptake of nutrients that leads to altered body composition (decreased fat free mass and body cell mass) leading to diminished physical and mental function and impaired clinical outcome from disease[2].

The nutrition status of an individual is a determinant of body composition and functional status. Deficient state negatively effects patient outcomes, increases morbidity and mortality, time spent in the hospital, readmission rates and costs, while decreasing the quality of life. Therefore, screening for risk factors associated with deficiencies and, when indicated, assessing an individual's nutrition status should be part of the evaluation of a patient.

Inflammatory bowel disease (IBD) is associated with inflammation and negative nutrient balance and thus carries a high risk of malnutrition. The prevalence of malnutrition in IBD varies between 5% and 75% and up to 36% newly diagnosed patients have been shown to be malnourished[3-5]. Patients with IBD have been shown to have higher PCM than healthy controls[6].Malnutrition is more common in patients with active disease as compared to healthy controls[7].

Pathogenesis:

1. Decreased Intake: Due to:
    - Symptoms such as nausea, abdominal pain, vomiting, and diarrhea.
    - Fasting due to hospitalization/procedures/scans.
    - Prolonged restrictive diets[8].
2. Inflammation: Inflammatory cytokines lead to impaired epithelial transport and loss of epithelial integrity[9].
3. Gastrointestinal loss:
    - Epithelial alteration
    - Alterations of ionic transports

- Intestinal ulceration[10].

4. Bile acid diarrhoea: Because of terminal ileal disease[11].
5. Medications:
   - Glucocorticoids: Recurrent and prolonged use lead on to deficiency of calcium, phosphorus, zinc, vitamin C and D.
   - Sulfasalazine: Afolate antagonist. Its long term use can cause anemia and hyper-homocysteinemia[12].
   - Cholestyramine: Causes fat malabsorption[13].
6. Parenteral Nutrition: Cause micronutrient deficiencies, including vitamins A, D, and E, zinc, copper, and selenium[14,15].
7. SIBO: Small intestinal bacterial overgrowth due to chronic intestinal inflammation or surgical removal of the ileocecal valve[16].
8. Surgery: It causes malabsorption by inducing diarrhoea by following mechanisms[17].
   - Reduced digestion and absorption of nutrients.
   - Ileal resection leads to reduced intestinal uptake of bile acids and causes bile salt diarrhoea.
   - Accelerating the intestinal transit.

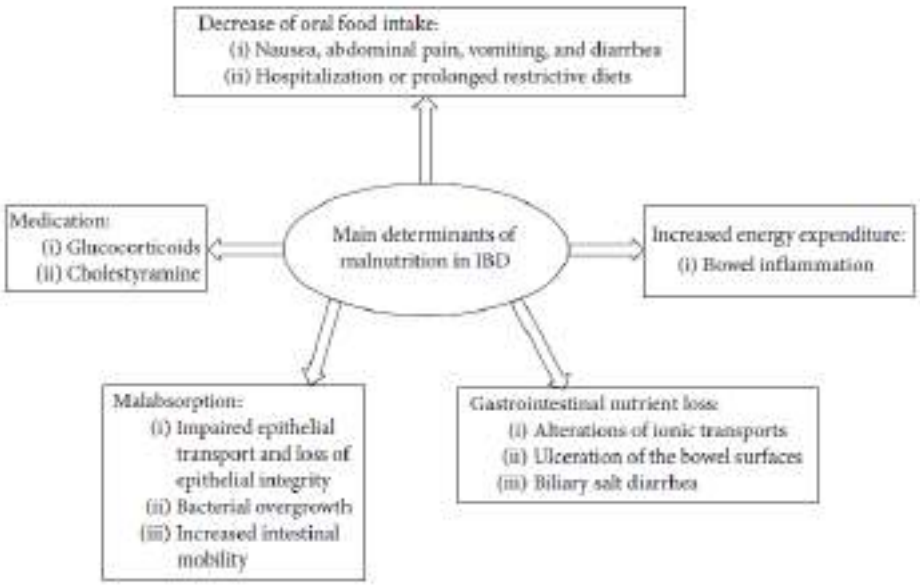

Decrease of oral food intake:
(i) Nausea, abdominal pain, vomiting, and diarrhea
(ii) Hospitalization or prolonged restrictive diets
Medication:
(i) Glucocorticoids
(ii) Cholestyramine
Main determinants of malnutrition in IBD
Increased energy expenditure:
(i) Bowel inflammation
Malabsorption:
(i) Impaired epithelial transport and loss of epithelial integrity
(ii) Bacterial overgrowth
(iii) Increased intestinal mobility
Gastrointestinal nutrient loss:
(i) Alterations of ionic transports
(ii) Ulceration of the bowel surfaces
(iii) Biliary salt diarrhea

Figure 1: Pathogenesis of Malnutrition in IBD[18]

CLINICAL ASPECTS OF MALNUTRITION

Malnutrition is associated with a poor clinical outcome in patients with IBD. The severity of malnutrition in IBD patients is dependent on the activity, duration, and extent of the disease and on the magnitude of the inflammatory systemic response[19].

Because involvement of small intestine is associated with a higher incidence of protein energy malnutrition and micronutrient deficiencies, so some differences exist in the nutritional status between UC and CD with CD usually presenting with more severe nutritional deficiencies[20].

Micronutrient deficiencies that commonly occur in IBD patients include iron, calcium, selenium, zinc, magnesium, B12, folic acid and fat-soluble vitamins[14].

Anemia is a common complication of IBD[21]. Iron deficiency is the main cause of anemia in the adult IBD population, with a prevalence between 36% and 90%[22]. The main factors determining iron deficiency in IBD are inadequate intake, active loss, impaired utilization and impaired uptake[23]. In active disease, hepcidin takes control of iron metabolism with development of anemia due to relative or absolute iron deficiency[24]. Other causes of anemia in IBD include folate and Vitamin B12 deficiency.

Low bone mass and osteoporosis is common in IBD patients. Causes include repeated exposure to steroids, extensive small-bowel disease or resection, chronic inflammation, low physical activity, and vitamin and micronutrient deficiencies. Vitamin D deficiency is present in around 70% of CD patients and up to 40% of UC patients[25]. Vitamin D deficiency may be involved in the pathogenesis of IBD[26]. Vitamin D helps in preserving mucosal integrity with mucosal healing capacity and its deficiency compromises mucosal barrier thereby increasing risk for mucosal damage and for IBD[27].

Folate deficiency occurs in 8.8% of UC patients and 28.8% of CD patients[28]. Causes include inadequate intake, decreased intestinal

surface area, drugs used in IBD such as sulfasalazine and methotrexate. Folate deficiency leads to hyper-homocysteinemia, which is responsible of the increased incidence of thromboembolic events in IBD patients[29].

Vitamin B12 deficiency is more common in CD than UC because of involvement of small intestine in the former. Selenium, zinc, and magnesium deficiencies commonly occur in IBD patients and present with bone health impairment, fatigue, poor wound healing and cartilage degeneration. Vitamin A deficiency occurs in up to 90% of IBD patients leading to poor wound healing, night blindness, and xerophthalmia. Vitamin K deficiency occurs because of frequent use of antibiotics and malabsorption[30,31].

OVERVIEW OF NUTRITIONAL ASSESSMENT

The assessment of nutritional status in IBD is the first step to identify malnutrition and/or sarcopenia status in order to set appropriate therapeutic regimens. A correct nutritional assessment provides quantitative and qualitative evaluations, so that nutritional support could be measured and evaluated over time.

Professional society guidelines recommend routine nutrition screening at hospital admission and, if indicated, nutrition assessment, but they differ in how these processes are defined. The European Society of Parenteral and Enteral Nutrition states, “The purpose of nutritional screening is to predict the probability of a better or worse outcome due to nutritional factors, and whether nutritional treatment is likely to influence this.” The American Society for Parenteral and Enteral Nutrition (ASPEN) refers to screening as a process to identify an individual who is malnourished or who is at risk for malnutrition to determine if a detailed nutrition assessment is indicated[32].Evaluation of malnutrition in patients with IBD involves nutritional screening and nutritional assessment. Nutritional screening refers to initial evaluation of an IBD patient to identify patients who are at risk of malnutrition. Nutritional assessment tools are then applied to at risk patients to

define their true nutritional status and after total assessment, appropriate intervention and nutritional rehabilitation is applied to malnourished patients.

Patients with IBD
Nutritional screening at the time of diagnosis (clinical history, nutritional screening tests)
No risk for malnutrition
At risk for malnutrition
Disease in remission
Active disease
Nutritional Assessment (patient history, food/nutrition related history, anthropometric measurements, nutrition-focused physical findings and biochemical tests)
Nutritional screening Annually
Nutritional screening Every 3 to 6 months
Confirmation of malnutirion / sarcopenia
Assessment of severity of malnutrition / sarcopenia
Nutritional Intervention and Rehabilitation
Reassess every 3 months till malnutrition / sarcopenia corrected
Nutritional screening every 3-6 months

Figure 2: Proposed Approach to Nutritional Status in IBD[33]

NUTRITION SCREENING TOOLS

Multiple NSTs have been developed in past decade for use in different clinical settings. An ideal NST includes parameters which are dynamic, like recent weight loss, BMI, and recent food intake, and also takes into

account the disease severity. The NSTs, when applied accurately and regularly, identify patients at risk of malnutrition who require referral to a nutrition specialist.

1. MIRT (Malnutrition Inflammation Risk Tool)
2. MUST (Malnutrition Universal Screening Tool)
3. SaskIBD (Saskatchewan Inflammatory Bowel Disease)
4. NRS 2002 (Nutrition Risk Screening 2002)
5. NRI (Nutritional Risk Index)
6. MNA-SF (Mini Nutritional Assessment-Short Form)

There is limited data on use of NSTs in IBD patients and more data are needed before definite recommendations are made.

The MIRT was developed as a simple tool composed of the objective parameters namely BMI, unintended weight loss and CRP in order to combine both nutrition- and inflammation-related measures. It has a total score of 8 points. Higher score values indicate more risk of malnutrition. A score of 0-2 indicates low risk of malnutrition whereas a score of ≥3 indicates high risk of malnutrition[34].

MUST, developed in the UK by the Malnutrition Advisory Group, was first developed for community medicine but it had good success on hospitals evaluations because of its simplicity, reliability, and validity. The nutritional risk is assessed BMI, assessment of unintentional weight loss in the last 3– 6 months, and the presence of any acute medical condition, in which there was an insufficient food intake calculated for a period equal to or greater than 5 days. The total score ranges from 0 to 2, indicating the presence of a mild, moderate, or severe risk of malnutrition (low risk = 0, moderate risk = 1, and severe risk = 2)[35].

SaskIBD: SaskIBD tool considers symptoms (nausea, vomiting, and diarrhea), nutrient intake (food intake and food avoidance), and unintentional weight loss, all of which are all well-defined risk factors for malnutrition in the IBD outpatient population. Its drawbacks include that

it does not capture disease severity and relies only on nutrition specific data It has a total score of 9 points. A score of 0-2 signifies low risk, 3-4 signifies medium risk and 5 or more score signifies high risk of malnutrition[36].

Nutrition Risk Screening 2002 (NRS 2002): It is used in hospital inpatients. Its parameters include BMI, Weight loss in past 3 months, Food intake in past week, Critical illness. It has a total score of 0-7.A score of equal to or more than 3 indicates high risk of malnutrition. The drawback of this score is that it requires trained staff and is not useful in outpatient setting[37].

Mini Nutritional Assessment-Short Form (MNA-SF): Its components are decreased food intake over past 3 months, weight loss in past 3 months, mobility, psychological or acute disease in past 3 months, neuropsychological disease, BMI or calf circumference. It is useful in hospital inpatients. It has a total score of 0–14. 0–7 score indicates malnourishment, 8–11 score indicates at risk of malnutrition and a score of 12–14 means normal nutritional status[38].

Nutritional Risk Index: This score is also useful in hospital inpatients. Its various components include albumin, ratio of present weight/usual weight (usual weight is defined as stable body weight for last 6 months). The patients with NRI score of >100 is considered no risk group, 97.5–100 mild risk, 83.5–97.5 moderate risk, and < 83.5 severe risk groups[39].

NUTRITION ASSESSMENT TOOLS

Nutritional assessment includes patient history, food/nutrition related history (e.g. dietary history), anthropometric measurements, nutrition-focused physical findings (e.g. physical appearance, fat and muscle store assessments), and biochemical data and disease specific tests.

Patient history

A detailed history is taken about the disease including disease characteristics, duration, behaviour (phenotype); comorbidities; family history of IBD; treatment history and social history.

Diet related history

Detailed dietary history including assessment of different aspects of diet such as energy and nutrient intake, intake of specific nutrients or food, dietary pattern and habits, frequency and composition of meals, and eating environment should be taken. The various tools used for dietary history include food frequency questionnaire (FFQ), 24-h diet recall, 3-day diet record, or daily diet diary [40].

Anthropometric measurements

BMI is an anthropometric measure that is basic in assessment of nutritional state of healthy and diseased persons. It is a cheap and convenient objective tool dependent on height and weight. It is calculated by body weight (in kilograms) divided by height in meter square. Asian population have different cut offs for BMI as compared to their European counterparts: Asia specific BMI cut offs are: < 18.5 kg/m^2 underweight, 18.5–22.9 kg/m^2 normal, 23.0–27.5 kg/m^2 overweight, and > 27.5 kg/m^2obese[41]. When used to predict an individual's health, rather than as a statistical measurement for groups, the BMI has limitations that can make it less useful than some of the alternatives, especially when applied to individuals with abdominal obesity, short stature, or unusually high muscle mass. In newly diagnosed obese IBD patient BMI is unlikely to be a true indicator of the nutritional status. But serial monitoring of BMI can accurately depict the changes in the nutritional state over a period of time. Although initially it was thought that low BMI was indicative of poor nutritional status, recent studies have focussed their attention on the increasing incidence of obesity and obesity as a risk factor for IBD[42]. Up to 32.7% of IBD patients are obese, and in particular up to 30.3% of CD patients and up to 35.2% of UC patients[42].

Obesity results in suboptimal response to therapy, potentially by promoting rapid clearance of biologic agents leading to low trough concentrations[43]. In a study by Flores et al it was found that IBD patients with BMI > 25 kg/m2 are less likely to need anti-TNF therapy than normal or underweight patients and are less likely to need surgery or hospitalization[42]. But Harper et al reported that high BMI in IBD patients is associated with a greater need for Infliximab escalation dose and with higher loss of response, need for steroid therapy, and number of hospitalization days compared to normal BMI patients[44].

Triceps skinfold thickness (TSFT) and mid-arm circumference (MAC) are relatively inexpensive, non-invasive and simple techniques for body composition assessment. Triceps skin fold thickness (TSFT) is a surrogate marker of subcutaneous fat thickness[45].

Mid upper arm circumference (MUAC) is measured at the mid-point between the tip of the shoulder (acromion process) and the tip of the elbow (olecranon process). MUAC ≤ 24 cm corresponds to a low BMI[46].

Physical examination and assessment

Subjective global assessment (SGA): It is commonly used tool for nutritional assessment. The seven-point SGA has a good correlation with BMI, body fat percentage, and mid upper arm muscle circumference. A score of 6–7 for most parameters indicates low risk for malnutrition, a score of 3–5 for most parameters indicates moderate malnutrition and a score 1–2 for most parameters indicates severely malnutrition[47]. It is more sensitive for detecting malnutrition as compared to the conventional three-point SGA. It has a good prediction with length of hospital stay and rates of non-elective re-admission[48].

Body composition analysis

Various components of body composition analysis include fat mass, fat free mass, body cell mass, lean body mass, skeletal muscle mass, total body water, extracellular water, intracellular water, and phase angle. These parameters are then used to calculate total body weight,

muscle fat, visceral fat area, and impedance. Various methods which can be used to measure body composition include dual-energy X-ray absorptiometry (DXA), magnetic resonance imaging (MRI), bioelectrical impedance analysis (BIA), ultrasound, computed tomography (CT), air displacement plethysmography, dilution methods, measurement of total body potassium, and in vivo neutron activation analysis. DXA is considered the gold standard for body composition analysis. Body composition is dependent on the activity, severity, and duration of disease. Both fat mass and fat-free mass are depleted in active disease, while only fat free mass is deficient in remission, indicating a poor recovery of lean mass in remission[49].

Sarcopenia assessment

It is done by measuring skeletal muscle mass and muscle strength.

The muscle mass can be calculated from DXA, BIA, CT, or MRI. MRI and CT provide best assessment of skeletal muscle, MRI being the gold standard. However MRI is costly. Therefore, single-slice MRI or CT performed at reference sites (most commonly L3 vertebra) for calculation of muscle cross-sectional area is taken as the surrogate marker for whole-body skeletal muscle[50]. The SMI (Smooth Muscle Index) varies with ethnicity. In a study by Benjamin et al the SMI cut offs of 36.54 cm^2/m^2 in males and 30.21 cm^2/m^2 in females have been reported on healthy adult organ donors from north India[51].

Up to 60% IBD patients have decreased muscle mass when compared with healthy subjects[52]. Adams et al. showed that a significant proportion of IBD patients affected by sarcopenia (41.5%) presented a normal body mass index (BMI) and, therefore, would not be identified as undernourished by traditional measures[53]. Sarcopenia has been associated with an increased need for surgery and poor surgical outcomes in IBD, as well as with osteopenia[54]. Low lean mass, sarcopenia, and low BMI are all independent positive predictors for osteopenia and osteoporosis[55].

Hand Grip Strength is measured using a hand-held Dynamometer. It is an excellent tool in determining fat free mass. It requires an alert and co-operative patient. Handgrip strength is widely used to measure muscle strength and it correlates with the leg strength, lower extremity power, and cross-sectional area of calf muscles. The highest of six squeeze readings, three with each arm and each squeeze lasting for 3–5 s, is taken as the final result. The Asian working group for sarcopenia (AWGS) has defined low muscle strength as handgrip strength < 28 kg for men and < 18 kg for women aged ≥65 years[56]. There is a lack of data on the normal hand grip strength in young Indian population.

Biochemical investigations

Biochemical micronutrient investigations complement NSTs, nutritional assessment, and clinical examination. Deficiencies of micronutrients impact disease activity, quality of life, and risk of carcinogenesis[57,58].

In a study by Jansen et al, 55 patients with CD in remission were examined at 0 and 6 months. They were assessed for disease activity by CDAI, Harvey–Bradshaw index: for inflammation by C-reactive protein (CRP), faecal calprotectin (FC): malnutrition by BMI, subjective global assessment (SGA), serum albumin, handgrip strength: body composition by bioelectrical impedance analysis and they administered 'Malnutrition Inflammation Risk Tool' (MIRT). All parameters were evaluated regarding their ability to predict disease outcome prospectively at 6 months. Their study showed that more than one-third of patients showed elevated inflammatory markers at baseline despite clinical remission (36.4% CRP ≥5mg/l, 41.5% FC ≥100 µg/g). Prevalence of malnutrition at baseline according to BMI, SGA and serum albumin was 2–16%. At 6 months, MIRT significantly predicted outcome in numerous nutritional and clinical parameters (SGA, CD-related flares, hospitalisations and surgeries). In contrast, SGA, handgrip strength, BMI, albumin and body composition had no influence on the clinical course. They concluded that MIRT was found to reliably predict clinical outcome in CD patients[59].

In a study by Cushing et al, 89 patients were included with acute severe UC, among whom 39 [43.8%] patients required medical rescue therapy or surgery. Two-thirds of the patients [70%] met the definition of sarcopenia i.e. skeletal muscle index of <55 cm2/m2 for men and <39 cm2/m2 for women [81% men, 48% women]. It was observed that patients with sarcopenia had similar disease characteristics and laboratory parameters to those with a normal muscle mass. However, a larger proportion of patients with sarcopenia required rescue therapy compared with those without (56% vs 28%). Neither visceral [p = 0.23] nor subcutaneous adiposity [p = 0.53] predicted the need for rescue therapy. They concluded that sarcopenia as determined on abdominal CT was a novel predictor of need for rescue therapy in hospitalized UC patients[60].

In a study by Rahman et al, 154 patients with IBD were studied over a 2 month period to study the association between the MUST scores and the Harvey Bradshaw Index (HBI) and the PMI (Partial Mayo Score), for CD and UC, respectively. A high MUST score was strongly associated elevated Harvey Bradshaw Index scores (p=0.005) for patients with Crohn's disease, but not with the Partial Mayo Index scores (p=0.597) for patients with ulcerative colitis. Nutritional risk scoring did not correlate with lower levels of disease activity. They noted significant associations in the odds of elevated nutritional risk and decreased albumin (OR 1.96, p<0.001), decreased Vitamin D (OR 1.51 p=0.032), and decreased creatinine (OR 1.47, p=0.050) and concluded that MUST predicts disease activity in patients with Crohn's disease[61].

In a study by Haskey et al on 110 patients with IBD, The Saskatchewan IBD–Nutrition Risk (SaskIBD-NR Tool) was developed and administered alongside the Malnutrition Universal Screening Tool (MUST). Nutrition risk was confirmed by the IBD dietitian (RD) and gastroenterologist (GI). Out of a total of 110 patients with IBD, 75 (68.2%) patients had Crohn's Disease and 35 (31.8%) had ulcerative colitis. Mean BMI was 26.4 kg/m2 (SD=5.8). RD/GI assessment

identified 23 patients (20.9%) at nutrition risk. The SaskIBD-NR tool classified 21 (19.1%) at some nutrition risk, while MUST classified 17 (15.5%). The SaskIBD-NR tool had significant agreement with the RD/GI assessment (k 0.83, p<0.001), while MUST showed a lack of agreement (k 0.15, p=0.12). The SaskIBD-NR had better sensitivity (82.6% vs 26.1%), specificity (97.7% vs 87.4%), positive predictive value (90.5% vs 35.3%), and negative predictive value (95.5% vs 81.7%) than the MUST. They concluded that SaskIBD-NR, which assesses GI symptoms, food restriction, and weight loss, adequately detects nutrition risk in IBD patients[62].

In a study by Sandhu et al to determine if patient self-administered malnutrition screening using the malnutrition universal screening tool (MUST) is reliable by comparing patient scores with those derived from the healthcare practitioner (HCP). A total of 154 adult outpatients with IBD were enrolled. The main outcome measure was chance-corrected agreement (κ) of malnutrition risk categorization. For patient-administered MUST, the chance-corrected agreement κ (95% confidence interval [CI]) was 0.83 (0.74–0.92) when comparing low-risk and combined medium- and high-risk patients with HCP screening. Weighted κ analysis comparing all 3 risks groups yielded a κ (95% CI) of 0.85 (0.77–0.93) between patient and HCP screening. All patients were able to screen themselves. Overall, 96% of patients reported the MUST questionnaire as either very easy or easy to understand and to complete. This study concluded that self-administered nutrition screening in outpatients with IBD is valid using the MUST screening tool and is easy to use[63].

In a study by Takaoka et al, nutritional status of 40 CD patients was assessed on admission using several screening tools and laboratory tests including Subjective Global Assessment, Nutrition Risk Screening 2002 (NRS 2002), Onodera's Prognostic Nutritional Index (O-PNI), Controlling Nutritional Status, serum albumin level, and weight loss Their validity was evaluated in relation to length of hospital stay (LOS) and intestinal resection. Prolonged LOS was correlated with each of

the screening parameters. Evaluation of prognostic yield showed cut off values of serum albumin 3.3 g/dL (AUC 0.797, sensitivity 57.1%, specificity 89.5%) and O-PNI 36.5 (0.749, 71.4%, 73.7%). By combining the serum albumin cut off value and NRS 2002 score, patients were divided into 4 groups, with a prolonged LOS rate of 68.2% in the group with the worst prognosis. It was concluded that a combination of serum albumin and NRS 2002 as nutritional screening tools may be useful for hospitalized CD patients[64].

In a study by Pizzoferrato et al, a total of 127 patients of IBD were enrolled and were evaluated for the percentage of sarcopenia in IBD patients, characterizing methods for assessment and clinical symptoms associated to it. Skeletal muscle mass was evaluated by Dual Energy X-ray Absorptiometry (DEXA) or Bioelectrical Impedance Analysis (BIA). Asthenia degree was assessed by subjective visual analogue scales (VAS). Quality of life was measured by the EQ-5D questionnaire. Patients with IBD showed a significant reduction in skeletal muscle mass than healthy controls with lower DEXA and BIA parameters. IBD patients presented a lower perception of muscle strength with a higher incidence of asthenia and reduction in quality of life when compared with healthy controls. A significant association between loss in skeletal muscle mass and high asthenia degree was found This study concluded that sarcopenia is common in IBD patients and it is associated with fatigue perception as well as a reduction in quality of life[65].

In a study by Knappe-Drzikova et al, nutritional status was assessed in 644 consecutively patients admitted with a wide variety of gastroenterological and hepatological Diagnosis. The study was aimed to assess the association between nutritional status parameters as characterized by Nutritional Risk Screening (NRS), anthropometry, serum transferrin, bioelectrical impedance analysis (BIA) and long-term overall survival in hospitalized gastroenterological & hepatological patients. Patients were followed for a mean period of 67 months (mean 54.8, range 0-107 months). During malnutrition screening, 475 (73.8%)

patients were diagnosed as sufficiently nourished by NRS (NRS 0-2), while an increased risk of malnutrition was found in 169 (26.2%) patients (NRS 3). Malnutrition was significantly associated with less favourable results for BMI ($p < 0.001$), serum transferrin ($p < 0.001$), BIA ($p < 0.001$), MAC ($p < 0.001$) and TST ($p < 0.05$). Overall 5-year survival rates were much shorter in malnourished patients whether with (43.9%) or without (73.6%) malignancy. By multivariable analysis the NRS ≥3 and, phase angle (PhA) over the 5th percentile or over the mean of the cohort were found to be associated with long-term survival. This study concluded that malnutrition is highly prevalent in hospitalized gastroenterological & hepatological patients and is associated with distinct clinical diagnoses. It was demonstrated that malnutrition characterized by the NRS, anthropometry, serum transferrin and BIA, not only predicts short-term but also significantly poor long-term outcome in these patients[66].

In a study by Fiorindi et al, 62 patients of IBD scheduled for elective surgery were enrolled. The IBD Nutritional Screening tool was developed to screen patients for further comprehensive assessment. NRS-2002, MUST, MST, MIRT, SaskIBD were compared with the new test. All screening tests were subsequently related to new GLIM criteria. According to GLIM criteria, 25 (40%) IBD patients were malnourished (15 CD and 10 UC, 33% vs. 63%, $p = 0.036$). Stage 1 malnutrition was reported in ten patients, while stage 2 was detected in 15 patients. The comparison of each nutritional risk tool with GLIM criteria showed sensitivity of 0.52, 0.6, 0.6, 0.84, 0.84 and 0.92 for SaskIBD, MUST, MST, NRS-2002, MIRT, and the new IBD nutrition screening tool, respectively. They concluded that in IBD, currently adopted nutritional screening tools are characterized by a low sensitivity when malnutrition diagnosis is performed with recent GLIM criteria[67].

In a retrospective study by Einav et al among IBD patients attending the IBD clinic, cases who had normal nutritional status and developed malnutrition between visits were compared to matched controls who

maintained normal nutritional status. Detailed information was gathered from medical files, including: demographics, disease phenotype, characteristics and activity, diet altering symptoms and comorbidities, medical and surgical history, annual healthcare utility, nutritional intake and the Malnutrition Universal Screening Tool (MUST) score. The independent risk factors identified were summed up to calculate the IBD malnutrition risk score. The interval between the physician consultations was 6.2 ± 3.0 months, during which cases lost 5.3 ± 2.3 kg of body weight and controls gained 0.2±2.3 kg ($p < 0.001$). Independent IBD-related malnutrition risk factors were: 18.5 ≤BMI ≤ 22 kg/m^2 (OR = 4.71, 95%CI 1.13–19.54), high annual healthcare utility (OR = 5.67, 95%CI 1.02–31.30) and endoscopic disease activity (OR = 5.49, 95%CI 1.28–23.56). The IBD malnutrition risk score was positively associated with malnutrition development independently of the MUST score (OR = 7.39, 95%CI 2.60–20.94). Among patients with low MUST scores determined during the index visit, identification of 2 IBD malnutrition risk factors was strongly associated with malnutrition development (OR = 8.65, 95%CI 2.21–33.82, $p = 0.002$)[68].

In a study by Ze Lan Lu et al in 150 patients with CD, BMI, body cell mass, body cell mass index, handgrip strength and handgrip strength index were all significantly decreased in the group of CD patients compared with controls [$p < 0.0001$]. When paired by BMI, healthy controls had significantly increased body cell mass index [$p = 0.0344$] and handgrip strength index [$p = 0.0010$] compared to patients. In addition, handgrip strength was well correlated with body cell mass [$r = 0.8365$, $p < 0.0001$]. This study concluded that handgrip strength index is an effective and convenient parameter to predict the functional nutritional status and muscular health in CD patients[69].

Nutritional aspects in inflammatory bowel disease are particularly relevant as they could potently contribute to disease morbidity and mobility. Results from the currently available literature show that a poor nutritional status, as well as selective malnutrition or sarcopenia, is associated with poor clinical outcomes, response to therapy and quality

of life. Several factors contribute to malnutrition in IBD patient. Early implementation of nutritional screening tools followed by a comprehensive nutritional assessment in at-risk patients is important to reduce the prevalence of malnutrition and improve clinical outcomes in the patients with IBD.

This study aims to see the nutritional status of patients with IBD using NSTs and NATs and find out if they have a positive relationship with disease course and complications.

MATERIALS AND METHODS

STUDY DESIGN

This study was conducted on the patients attending the outpatient department in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India.

Patients already diagnosed with IBD and newly diagnosed patients attending the outpatient in Department of Gastroenterology, DMC & H were enrolled for the study.

Patients suffering from IBD were enrolled after obtaining informed consent. Patients were divided into two groups:

1. Already diagnosed and in clinical remission: 100 patients – Group A

2. Newly diagnosed patients: 25 – Group B

New patients were diagnosed with colonoscopy/sigmoidoscopy, histopathological biopsy and/or CT enterography/MR enterography (where required).

Already diagnosed patients were classified in remission by CDAI (Crohn's Disease Activity Index) for Crohn's Disease and Total Mayo score for Ulcerative Colitis at baseline.

For remission CDAI should be less than 150 for CD and total mayo score should be equal to or less than 2 for UC.

Nutritional status was studied in patients by Nutrition Screening Tools (NST) and Nutrition Assessment Tools (NAT). NST's included MIRT (Malnutrition Inflammation Risk Tool), MUST (Malnutrition Universal Screening Tool) and SASK IBD whereas NAT included anthropometry parameters like height, weight, BMI, mid arm circumference, triceps skinfold thickness: biochemical markers like serum albumin, haemoglobin: sarcopenia assessment using handgrip strength and CT MSI (If available).

Baseline values were obtained for each patient and patients were followed up every three months for 1 year to monitor disease progression, complications, and relapse.

The subjects were continued on their standard of care pharmacological maintenance regimen with 5-ASA compounds/ immunomodulators.

SOURCES OF DATA

Consecutive patients suffering from IBD who were on remission and newly diagnosed IBD patients attending the outpatient or admitted indoors in Department of Gastroenterology, DMC & H were enrolled for the study.

METHODS OF COLLECTION OF DATA

Confirmed cases of IBD were enrolled and their nutritional status assessed using MIRT, MUST and SASK IBD. Patients were followed-up every 3 months till a total period of one year for disease characteristics at baseline, course, complications and mortality. Subjects were continued on their standard pharmacotherapy.

- **INCLUSION CRITERIA**

1 Age >18 years
2 Confirmed IBD patients who were in remission
3 Newly diagnosed IBD patients
4 Able to give informed consent and/or assent as appropriate

- **EXCLUSION CRITERIA**

1 Patients in relapse
2 Patients unwilling or unable to give consent or participate in all study requirements

SCALES AND SCORES

The Mayo Score for ulcerative colitis disease activity provides an assessment of disease severity and can be used to monitor patients during therapy. The score can range from 0-12 with higher scores indicating worse severity. A score of equal to or less than 2 indicates

remission, 3-5 indicates mild disease, 6-10 indicate moderate disease and ≥11 indicate severe UC.

Figure 3: TOTAL MAYO SCORE[70]

A=Stool Frequency
0 = Normal
1 = 1–2 stools/day more than normal
2 = 3–4 stools/day more than normal
3 = >4 stools/day more than normal

B=Rectal Bleeding
0 = None
1 = Streaks of blood with stool less than half the time
2 = Visible blood with stool half of the time or more
3 = Passing blood alone

C=Physician Global Assesment
0 = Normal
1 = Mild disease
2 = Moderate disease
3 = Severe disease

D=Endoscopic Mayo Score
0 = Normal or inactive disease
1 = Mild disease (erythema, decreased vascular pattern, mild friability
2 = Moderate disease (marked erythema, absent vascular pattern, friability, erosions)
3 = Severe disease (spontaneous bleeding, ulceration)

MAYO SCORE= A+B+C+D

The Crohn's Disease Activity Index (CDAI) combines weighted scores of clinical and laboratory variables to estimate disease severity. CDAI scores of less than 150 indicate a clinical remission and score of 151-220 indicates mild disease, 221-450 indicate moderate disease severity and ≥451 indicate severely active disease. Main components of the CDAI are patient-reported symptoms such as diarrhoea, abdominal pain and overall well-being referring to the last week before assessment. Furthermore, it includes the presence of extra-intestinal manifestations, haematocrit and ratio of actual body weight: standard body weight.

Figure 4: Crohn's Disease Activity Index[71]

Clinical or laboratory variable	Weighting factor
Number of liquid or soft stools each day for 7 days	× 2
Abdominal pain (graded from 0 to 3 based on severity) each day for 7 days	× 5
General wellbeing, subjectively assessed from 0 (well) to 4 (terrible) each day for 7 days	× 7
Complications*	× 20
Use of diphenoxylate or opiates for diarrhea	× 30
An abdominal mass (0 for none; 2 for questionable; 5 for definite)	× 10
Absolute deviation of hematocrit from 47% in men and 42% in women	× 6
Percentage deviation from standard weight	× 1

*One point is added for each set of complications: arthralgia or frank arthritis; inflammation of the iris or uveitis; erythema nodosum, pyoderma gangrenosum, or aphthous ulcers; anal fissures, fistulas, or abscesses; other fistulas; and fever (>100 °F) during the previous week.

MIRT is composed of the objective parameters BMI, unintended weight loss and CRP in order to combine both nutrition- and inflammation-related measures. It has a total score of 8 points. Value ≥3 indicate more risk of malnutrition.

Figure 5: Malnutrition Inflammation Risk Tool (MIRT)[59]

		Points		Points		Points
BMI (kg/m²)	>20	0	18·5–20·0	1	<18·5	2
Weight loss 3 months (%)	<5	0	5–<10	2	≥10	3
CRP (mg/l)	<5	0	5–50	2	≥50	3

* Score: 0–8 points.

MUST is a five-step screening tool to identify adults, who are malnourished, at risk of malnutrition (undernutrition), or obese. It is for use in hospitals, community and other care settings and can be used by all care workers.

Step 1: Measure height and weight to get a BMI score.

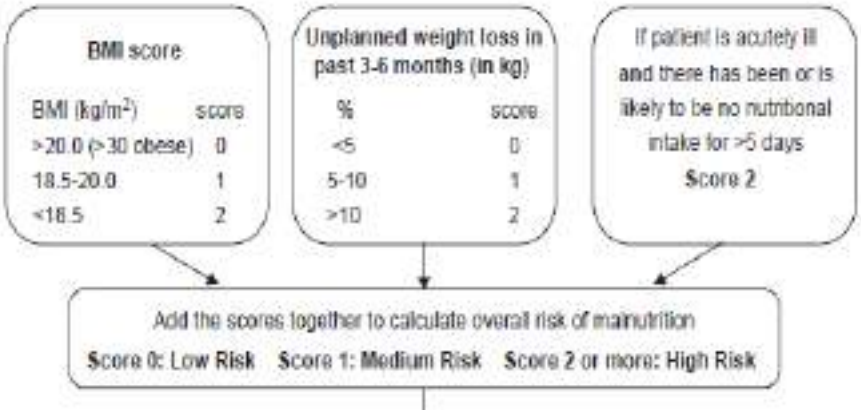
Step 2: Note percentage unplanned weight loss and score using tables provided.

Step 3: Establish acute disease effect and score.

Step 4: Add scores from steps 1, 2 and 3 together to obtain overall risk of malnutrition. Total score of 0 signifies low risk, score of 1 signifies medium risk and score of 2 or more signifies high risk of malnutrition.

Step 5: Use management guidelines and/or local policy to develop care plan.

Figure 6: Malnutrition Universal Screening Tool (MUST)[72]


BMI score
BMI (kg/m²) score
>20.0 (>30 obese) 0
18.5-20.0 1
<18.5 2
Unplanned weight loss in past 3-6 months (in kg)
% score
<5 0
5-10 1
>10 2
If patient is acutely ill and there has been or is likely to be no nutritional intake for >5 days
Score 2
Add the scores together to calculate overall risk of malnutrition
Score 0: Low Risk Score 1: Medium Risk Score 2 or more: High Risk

SaskIBD nutrition risk tool considers symptoms (nausea, vomiting, and diarrhoea), nutrient intake (food intake and food avoidance), and unintentional weight loss, all of which are all well-defined risk factors for malnutrition in the IBD outpatient population. It has a total score of 9 points. A score of 0-2 signifies low risk, 3-4 signifies medium risk and 5 or more score signifies high risk of malnutrition.

Figure 7: Saskatchewan IBD (SaskIBD)[62]

Nutrition screening item	Score
1. Have you experienced nausea, vomiting, diarrhea or poor appetite for greater than two weeks?	"no symptoms" =0, "1-2 symptoms" =1, "≥3 symptoms" =2
2. Have you lost weight in the last month without trying?	"no" =0, "unsure" =1, "yes" =see below
IF YES, how much weight have you lost?	"<5 lbs." =0, "5-10 lbs." =1, "10-15 lbs." =2, ">15 lbs." =3
3. Have you been eating poorly because of a decreased appetite?	"no" =0, "yes" =2
4. Have you been restricting any foods or food groups?	"no" =0, "yes" =2

Total score: 0-2=low risk, 3-4=medium risk, ≥5=high risk.

DURATION OF STUDY

Patients were enrolled from April 2020 to September 2020 and were followed up every three months for a period of 1 year till August 2021.

OUTCOME

Primary Outcome

To study the nutritional status in patients with Inflammatory Bowel Disease.

Secondary Outcome

To study the correlation of nutritional status with disease course and complications.

STATISTICAL ANALYSIS

Data was described in terms of range; mean±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency was less than 5. A probability value (p value)less than 0.05 was considered statistically significant. All statistical calculations were done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

OBSERVATION AND RESULT

This study was conducted on the patients attending the outpatient department in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India. One hundred and twenty five patients were enrolled during the study period. Of these, 100 were those who were already diagnosed with IBD in remission (Group A) and 25 were newly diagnosed IBD patients (Group B). Six patients were lost to follow-up at the first visit (3 each in Group A and B) and twelve more were lost to follow up at 1 year (9 in Group A and 3 in Group B).

All patients enrolled in the study were initially screened using Nutrition Screening Tools: MIRT, MUST and SASK IBD. Thereafter, all these patients also underwent a detailed assessment for the nutritional status using Nutrition Assessment Tools: anthropometric data, handgrip strength, haemoglobin and albumin levels. Patients were followed-up for the clinical course of disease at 3 monthly intervals till 1 year in person and clinical outcomes like maintenance/attainment of remission, disease flare-ups, hospitalisations, surgery and death/mortality were assessed. The following observations were made:

1. **Age distribution of patients:** Mean age of patients in both groups was comparable (Group A 40.46 ± 13.13 years, Group B 39.52 ± 13.90 years, p=0.736). The youngest patient was 18 years and oldest was 71 years. A majority of patients were in the 30-50 age group in both groups A and B. Number of patients in <30 years age group were 23 (23%) in Group A and 7 (28%) in Group B respectively, in 30-50 age group were 54 (54%) in Group A and 11 (44%) in Group B respectively, in >50 age group were 23 (23%) in Group A and 7 (28%) in Group B respectively.

TABLE 1: AGE DISTRIBUTION OF PATIENTS

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
Age group (years)	< 30	23	23%	7	28%	30
	30-50	54	54%	11	44%	65
	> 50	23	23%	7	28%	30
Total		100	100%	25	100%	125

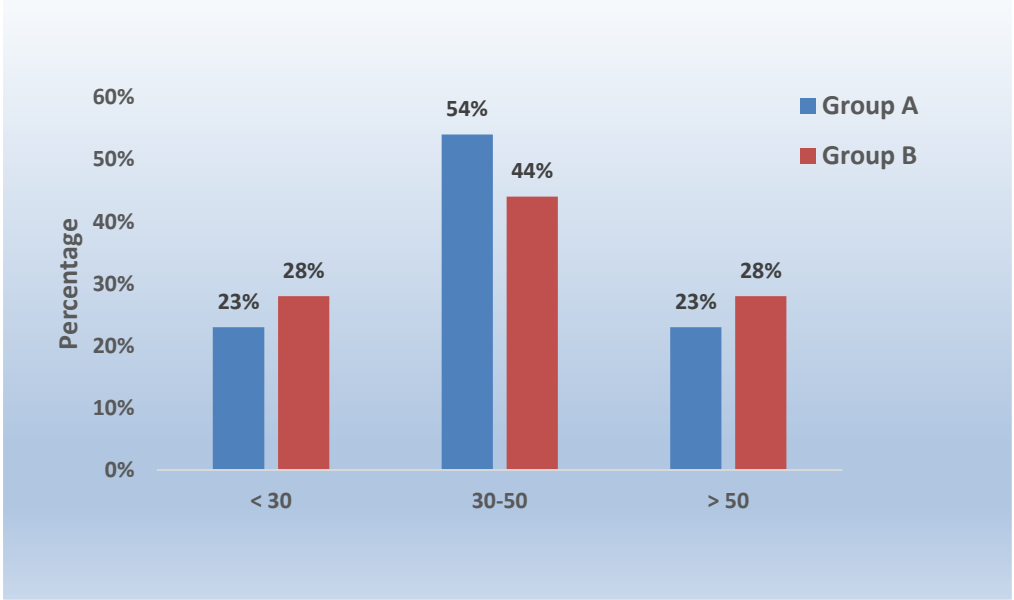


FIGURE 8: AGE DISTRIBUTION OF PATIENTS

2. **Sex distribution of patients:** A female preponderance was seen, with a F:M ratio of 1.2:1. The F:M ratio was 1.19:1 in Group A and 1.27 in Group B (p=0.234).

TABLE 2: SEX DISTRIBUTION OF PATIENTS

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
Sex	F	54	54%	14	56%	68
	M	46	46%	11	44%	57
Total		100	100%	25	100%	125

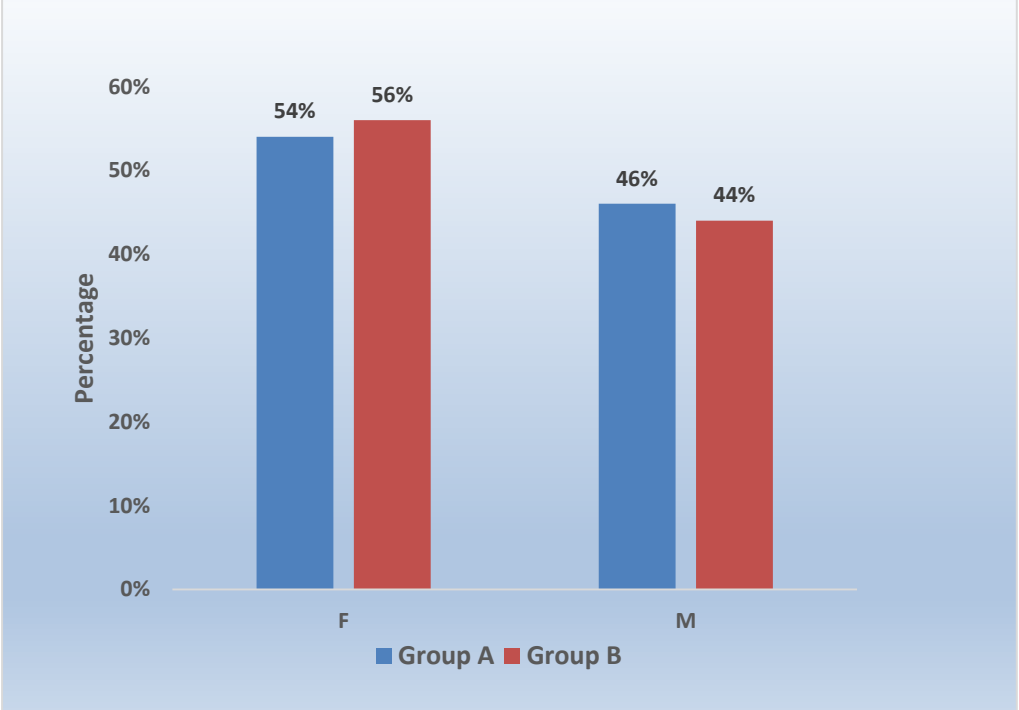


FIGURE 9: SEX DISTRIBUTION OF PATIENTS

3. **IBD type:** UC (n=101, 80.8%) was more common than CD (n=24, 19.2%), with a UC:CD ratio of 4.2:1. In Group A, 82 patients had UC and 18 patients had CD (UC:CD=4.5:1) whereas in group B, 19 patients had UC and 6 patients had CD(UC:CD=3.1:1).

TABLE 3: DISTRIBUTION ACCORDING TO IBD TYPE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
IBD Type	UC	82	82%	19	76%	101
	CD	18	18%	6	24%	24
Total		100	100%	25	100%	125

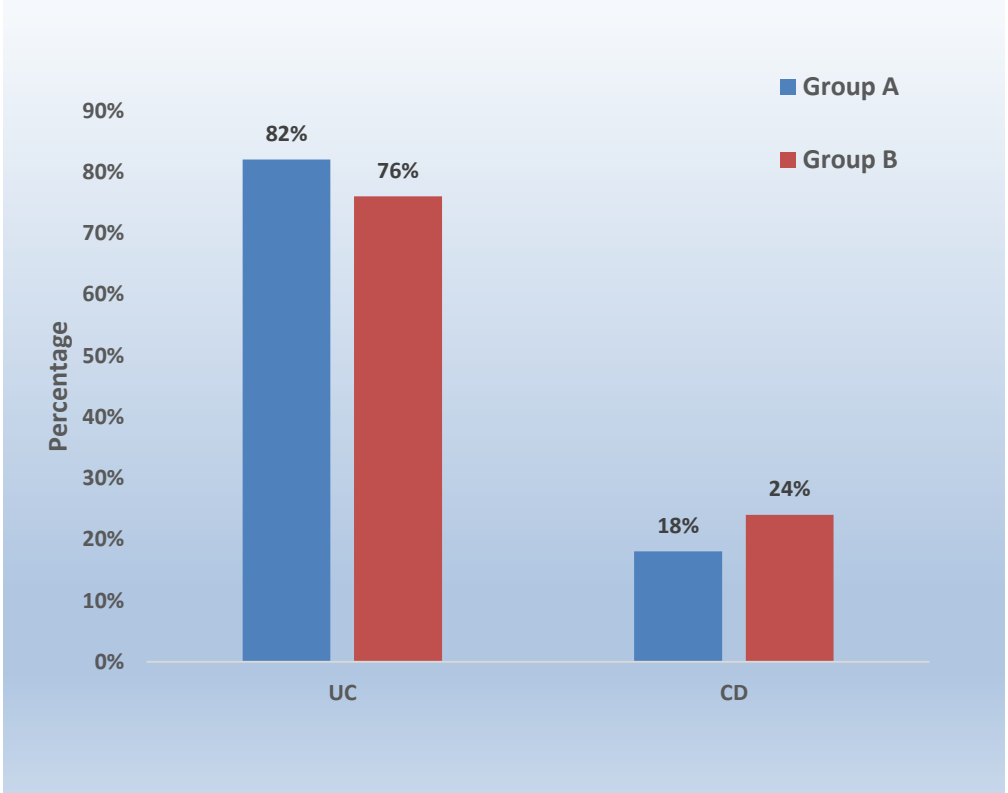


FIGURE 10: DISTRIBUTION ACCORDING TO IBD TYPE

4. **Disease severity at baseline:** In patients with CD the mean CDAI score of CD patients in Group A was 115.83 ± 24.20 (all patients were in remission) and in Group B was 326.67 ± 104.00 (mild disease CDAI 151-220, n=1; moderate disease CDAI 221-450, n=5) (p=0.001). None of the patients had severe disease (CDAI >450).

TABLE 4 A: CROHN'S DISEASE SEVERITY AT BASELINE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
CDAI GROUP	0-150	18	100%	0	0%	18
	151-220	0	0	1	17%	1
	221-450	0	0	5	83%	5
Total		18	100%	6	100%	24

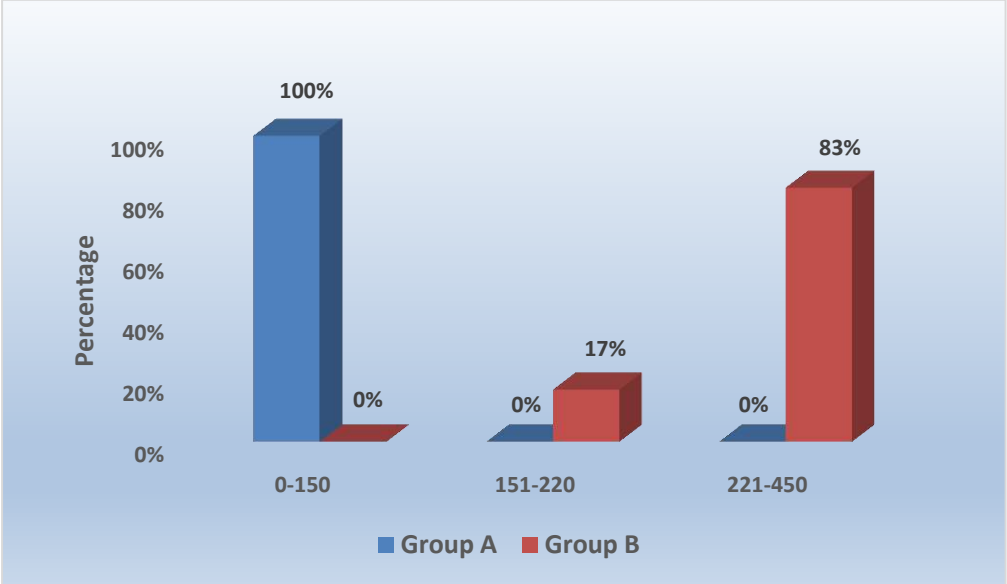


FIGURE 11: CROHN'S DISEASE SEVERITY AT BASELINE

In patients with UC, the mean Mayo Clinic Score of in Group A was 1.99 ± 0.11 (all in remission) and in Group B was 7.32 ± 1.67 (p=0.001). In Group B, 4 patients had mild disease with (Mayo Score of 3-5) and 15 patients had moderately severe disease severity (Mayo Score of 6-10). None of the patients had severe disease (Mayo Score of ≥10.)

TABLE 4B: ULCERATIVE COLITIS DISEASE SEVERITY AT BASELINE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
	0-2	82	100%	0	0%	82
Mayo Score	3-5	0	0%	4	21%	4
	6-10	0	0%	15	79%	15
Total		82	0	19	100%	101

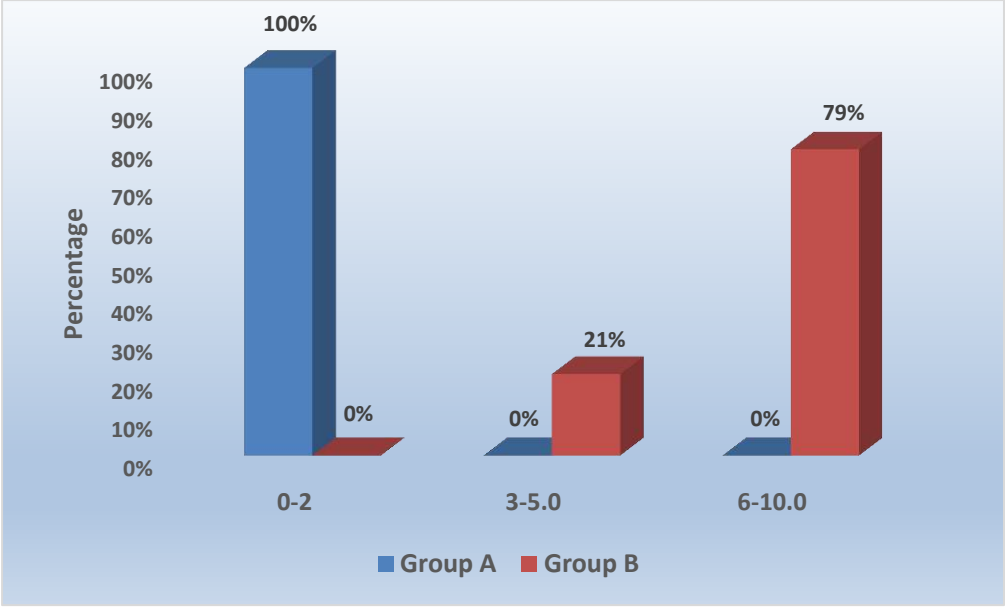


FIGURE 12: ULCERATIVE COLITIS DISEASE SEVERITY AT BASELINE

5. **Disease Extent at Baseline:** Amongst the patients with UC, 82 patients belonged to Group A, of which 11 (12.5%) had E1 disease, 63 (76.82%) had E2 disease and 8 (9.76%) had E3 disease at baseline. Nineteen patients belonged to Group B, of which 15 (78.94%) had E2 disease and 4 (21.05%) patients had E3 disease.

   In patients with CD, 18 patients belonged to Group A, 6 (33.3%) of these had ileal disease (L1), 5 (27.8%) had colonic disease (L2) and 7 (38.9%) had ileo-colonic (L3) disease. Of the 6 patients in Group B, 1 (16.7%) had ileal disease (L1), 3 (50%) had colonic disease (L2) and 2 (33.3%) had ileo-colonic (L3) disease.

TABLE 5: DISEASE EXTENT AT BASELINE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
Extent of UC	E1	11	12.5%	0	0%	11
	E2	63	76.82%	15	78.94%	78
	E3	8	9.76%	4	21.05%	12
Total		82	100%	19	100%	101

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
Extent of CD	L1	6	33.3%	1	16.7%	7
	L2	5	27.8%	3	50%	8
	L3	7	38.9%	2	33.3%	9
Total		18	100%	6	100%	24

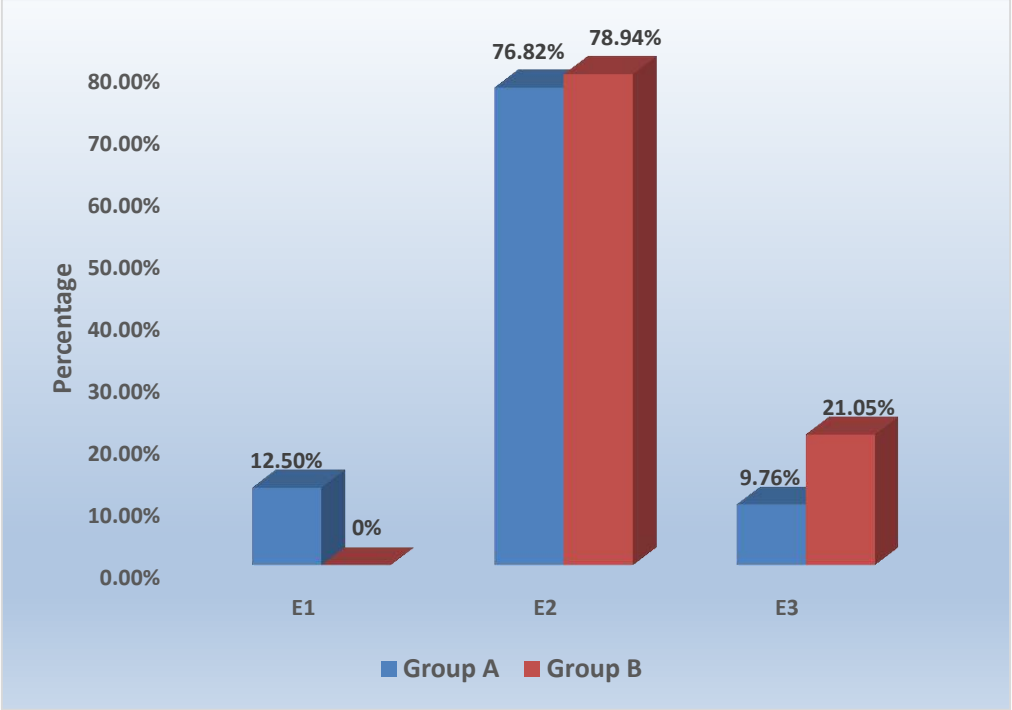


FIGURE 13: EXTENT OF UC

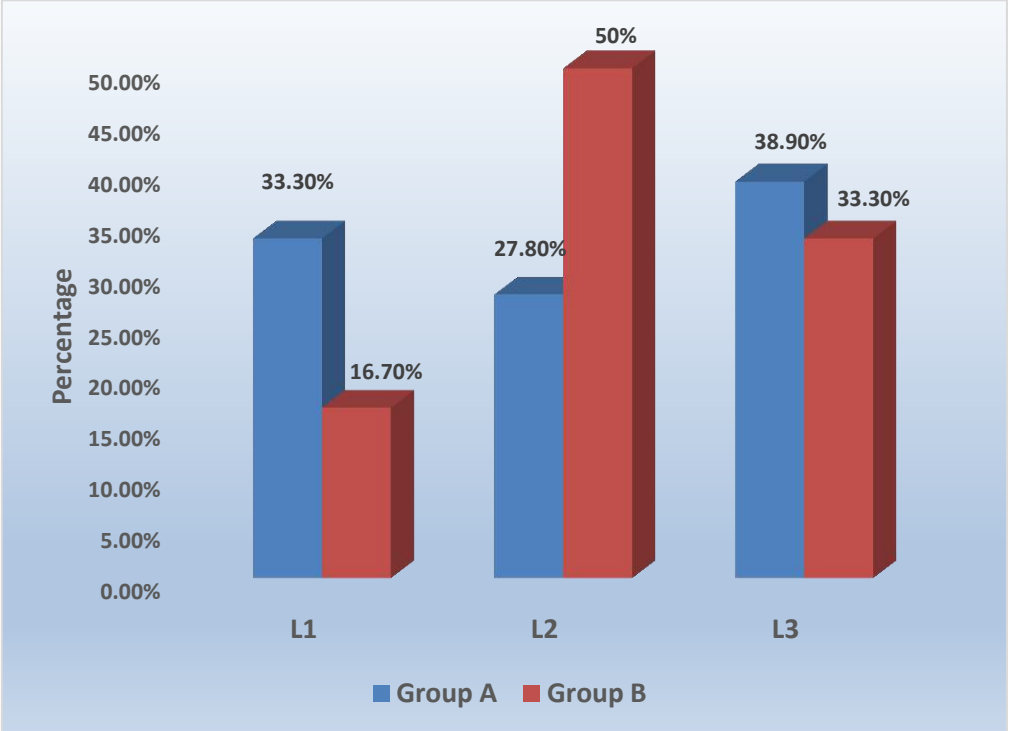


FIGURE 14: EXTENT OF CD

6. **Comorbidities:** Out of 125 patients, 18 (14.4%) patients had comorbidities. 10 patients had hypertension, 3 had diabetes, 4 had hypothyroidism, 2 had celiac disease and 1 had bronchial asthma. Most of the patients had a single comorbidity except 2 patients who had two comorbidities

TABLE 6: COMORBIDITIES

Co-morbidities	No. of cases	Percentage
Bronchial Asthma	1	0.8%
Celiac Disease	2	1.6%
Hypothyroidism	4	3.2%
Diabetes	3	2.4%
Hypertension	10	8.0%
No Comorbidity	107	85.6%

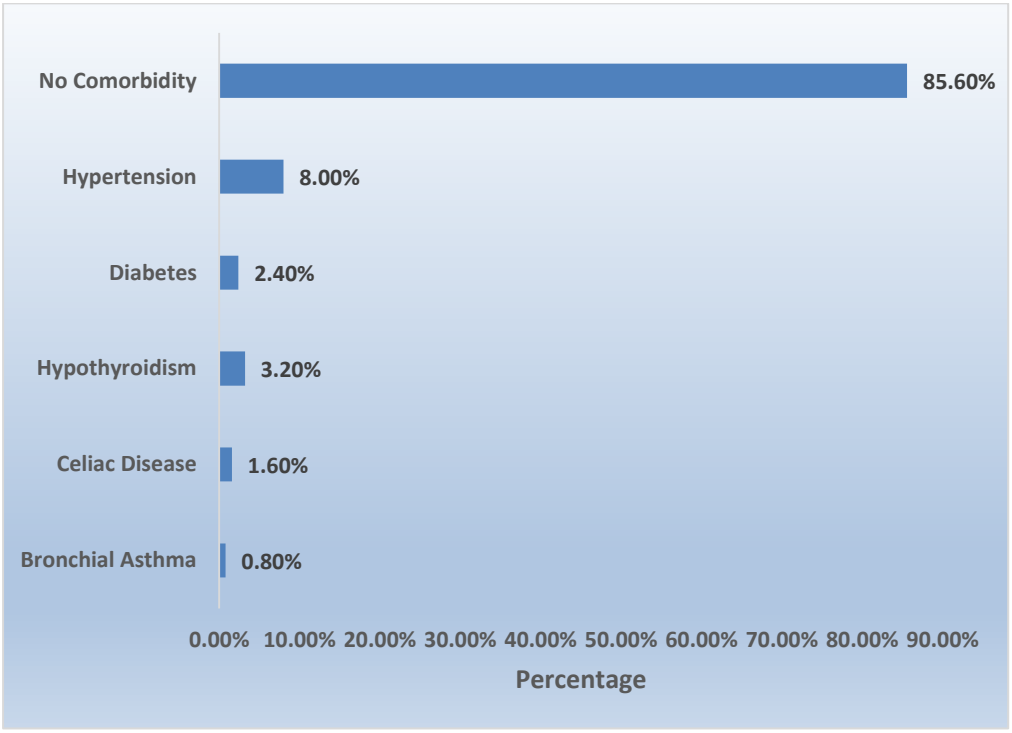


FIGURE 15: COMORBIDITIES

7. **Medications at baseline:** In Group A, all patients were on 5-ASA compounds, 26 patients were on azathioprine and none of the patients were on steroids. 24 patients had previous exposure to oral steroids and 18 patients had previous exposure to intravenous steroids as well.

   In Group B, all patients were on 5-ASA compounds, 15 patients were on oral steroids and 5 patients were on azathioprine.

TABLE 7: MEDICATIONS AT BASELINE

	Group A	Group B
5-ASA	100	25
Azathioprine	26	5
Oral Steroids	0	15
Previous Exposure to Oral Steroids	24	0
Previous Exposure to Intravenous Steroids	18	0

8. **Duration of disease:** The average disease duration of IBD in patients in Group A in the study was 6.67 ± 5.97 years. In Group A, 54 (54%) patients had the disease for 0-5 years, 26 (26%) patients had disease for 6-10 years and 20 (20%) patients had the disease for more than 10 years. In Group B, all patients were newly diagnosed patients of IBD.

TABLE 8: DURATION OF DISEASE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
Disease Duration group	New	0	0%	25	100%	25
	1-5yrs	54	54%	0	0%	54
	6-10yrs	26	26%	0	0%	26
	≥10yrs	20	20%	0	0%	20
Total		100	100%	25	100%	125

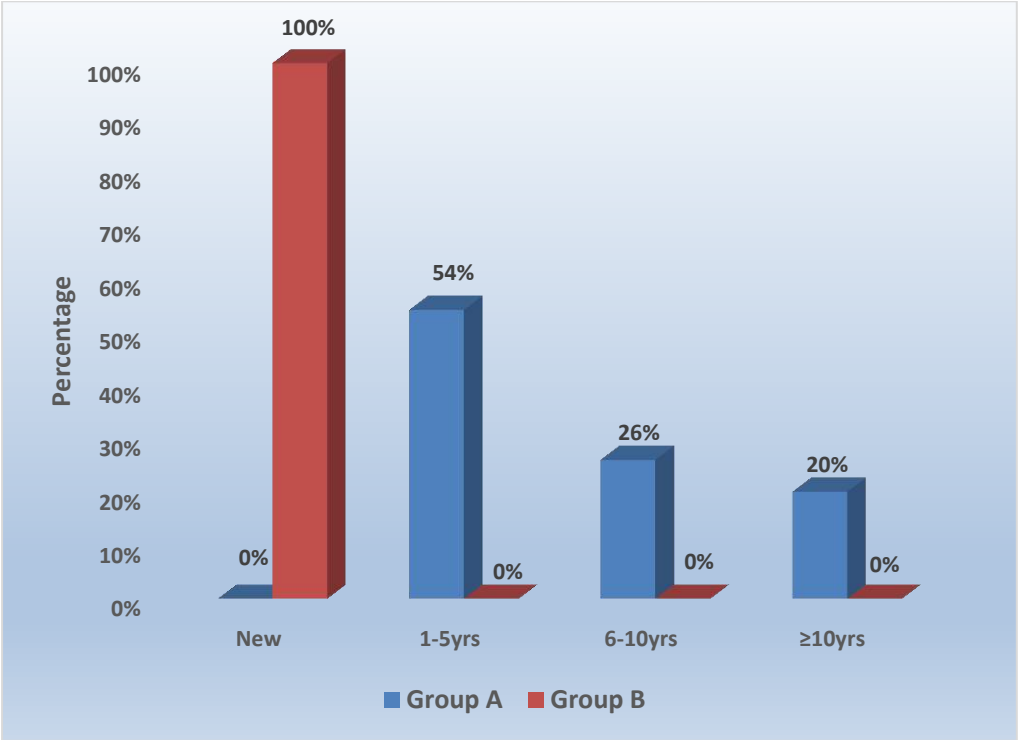


FIGURE 16: DURATION OF DISEASE

9. **BMI at Baseline(kg/m^2):** The mean BMI of patients in Group A was 24.22 ± 4.74 kg/m^2 and that of patients in Group B was 22.24 ± 5.20 kg/m^2(p= 0.018). In Group A, 11 (11%) patients were underweight (BMI <18.5 kg/m^2), 33 (33%) patients had normal BMI (BMI 18.5-22.9 kg/m^2), 39 (39%) patients were overweight (BMI 23-27.5 kg/m^2) and 17 (17%) patients were obese (BMI >27.5 kg/m^2). In Group B, 4 (16%) patients were underweight (BMI <18.5 kg/m^2), 14 (56%) patients had normal BMI (18.5-22.9 kg/m^2), 3 (12%) patients were overweight (BMI of 23-27.5 kg/m^2) and 4 (16%) patients were obese (BMI of >27.5 kg/m^2).

TABLE 9: BMI AT BASELINE

		Group A		Group B		Total
		No. of cases	%age	No. of cases	%age	
BMI (kg/m^2)	< 18.5	11	11%	4	16%	15
	18.5-22.9	33	33%	14	56%	47
	23-27.5	39	39%	3	12%	42
	> 27.5	17	17%	4	16%	21
Total		100	100%	25	100%	125

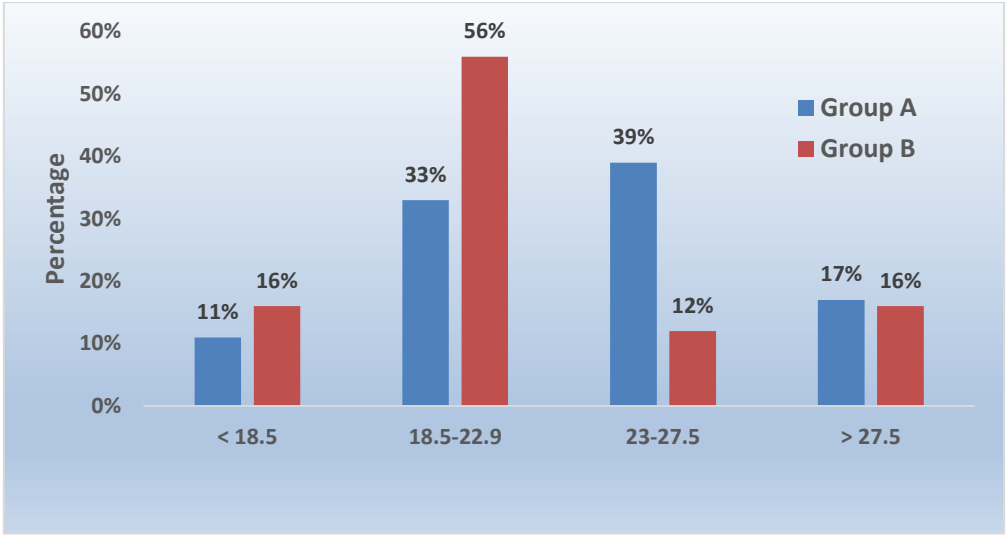


FIGURE 17: BMI AT BASELINE

10. **Comparing Nutrition Parameters at Baseline between Group A and B (TABLE 10):** NSTs including MIRT, MUST and SASK IBD suggested significantly higher risk of malnutrition in patients in group B ($p<0.05$). All these patients also underwent NATs, and patients in group B were found to have significantly lower BMI and MAC ($p<0.05$). Other NATs like Hand Grip Strength, Triceps Skin Fold Thickness, Skeletal Muscle Area, SMI, Haemoglobin and albumin did not report any significant difference in the nutritional status of patients in either group. Inflammatory markers (CRP) were significantly higher in Group B.

TABLE 10: COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN GROUP A & GROUP B

	Group A		Group B		Z	p-value
NSTs	Mean	SD	Mean	SD		
MIRT	0.88	1.02	2.04	1.59	-3.748	0.000
MUST	0.63	0.81	1.36	1.19	-2.977	0.003
SASK IBD	2.05	1.21	3.44	1.04	-4.736	0.000
NATs						
Age	40.46	13.13	39.52	13.90	-0.337	0.736
BMI(kg/m^2)	24.22	4.74	22.24	5.20	-2.365	0.018
MAC(cm)	26.57	3.27	24.98	3.14	-2.146	0.032
Hand Grip Strength(kg)	29.23	10.11	25.96	10.36	-1.313	0.189
Triceps Skin Fold Thickness(mm)	14.10	7.47	11.44	7.90	-1.806	0.071
Skeletal Muscle Area(cm^2)	103.20	27.06	97.12	21.29	-0.345	0.730
SMI(cm^2/m^2)	18.63	20.44	21.72	20.51	-0.793	0.428
Hb(g/dL)	10.92	1.62	11.31	2.06	-1.132	0.258
CRP(mg/L)	3.98	4.96	13.95	14.29	-5.084	0.001
Albumin(g/dL)	3.40	0.42	3.28	0.40	-1.347	0.178

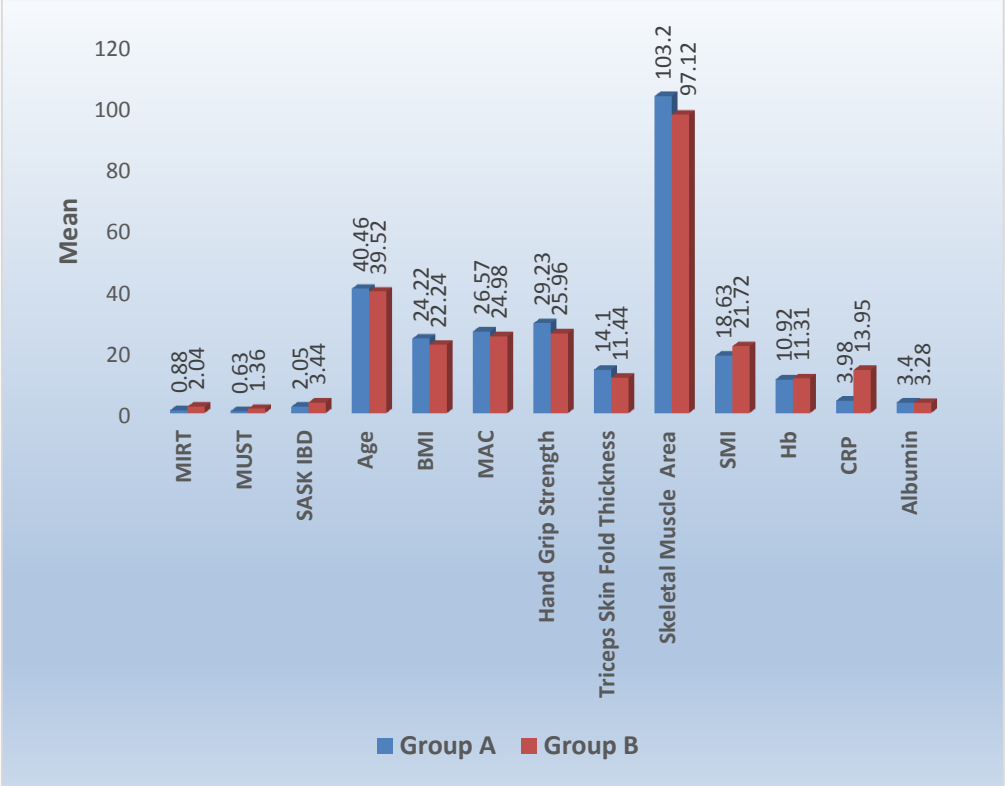


FIGURE 18: COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN GROUP A & GROUP B

11. **Comparison of Nutrition Parameters between UC & CD patients**: None of the nutrition screening or assessment parameters showed any significant difference in the nutritional status of UC and CD patients at baseline assessment.

TABLE 11: COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN UC & CD PATIENTS

Total Patients	UC		CD		Z	p-value
NSTs	Mean	SD	Mean	SD		
MIRT	1.12	1.14	1.08	1.61	-0.719	0.472
MUST	0.78	0.91	0.75	1.07	-0.462	0.644
SASK IBD	2.34	1.26	2.29	1.49	-0.203	0.839
NATs						
Age	39.58	13.26	43.17	13.01	-1.201	0.230
BMI(kg/m^2)	23.63	4.81	24.63	5.19	-0.902	0.367
MAC(cm)	26.11	3.36	26.85	2.98	-1.316	0.188
Hand Grip Strength(kg)	28.50	10.22	28.92	10.35	-0.182	0.856
Triceps Skin Fold Thickness(mm)	13.17	7.32	15.25	8.67	-0.942	0.346
Skeletal Muscle Area(cm^2)	102.53	27.32	98.89	19.07	-0.116	0.908
SMI(cm^2/m^2)	19.37	20.67	18.72	19.71	-0.074	0.941
Hb(g/dL)	10.93	1.52	11.28	2.38	-1.451	0.147
Albumin(g/dL)	3.35	0.41	3.46	0.43	-1.135	0.256

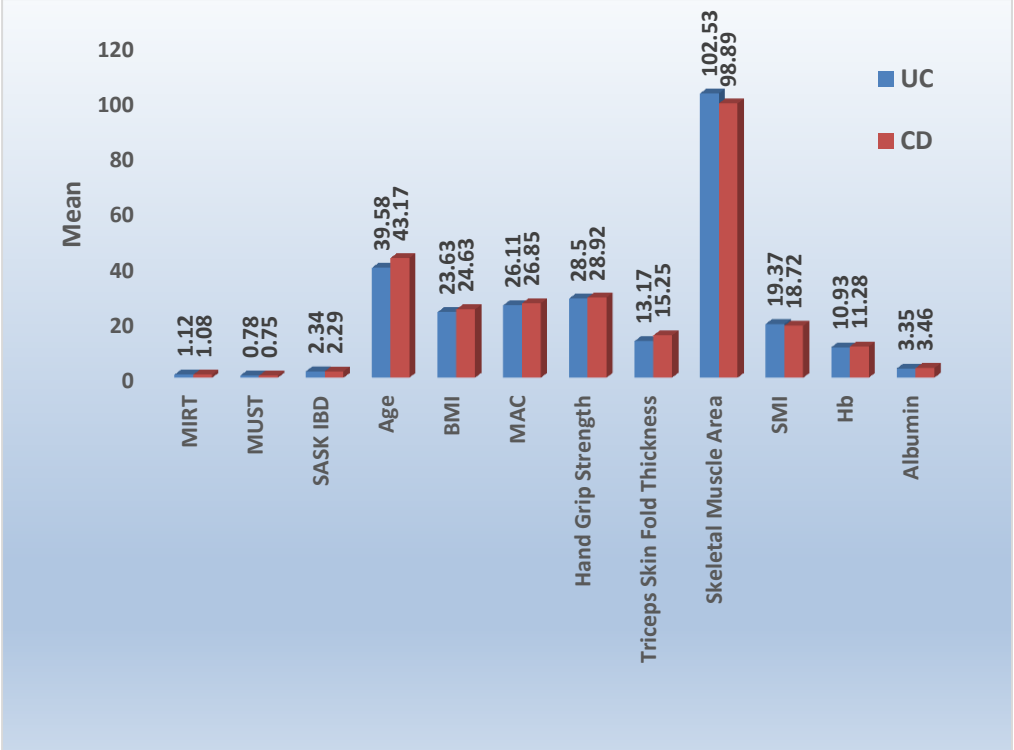


FIGURE 19: COMPARISON OF NUTRITION PARAMETERS AT BASELINE BETWEEN UC & CD PATIENTS

12. **Comparing Nutrition Parameters in UC and CD patients between Group A and B at baseline:**

Ulcerative Colitis: When screened using nutrition screening tools like MIRT, MUST and SASK IBD, UC patients in Group B were found to be at a significantly higher risk of malnutrition as compared to Group A.

On detailed assessment using NATs, UC patients in Group B were found to have significantly lower BMI, MAC and Triceps Skinfold Thickness, while Hand Grip Strength, Skeletal Muscle Area, Haemoglobin and Albumin were comparable between the 2 groups.

TABLE 12A: COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN UC PATIENTS IN BOTH GROUPS

UC	Group A		Group B		Z	p-value
NSTs	Mean	SD	Mean	SD		
MIRT	0.95	1.04	1.84	1.30	-3.200	0.002
MUST	0.66	0.80	1.32	1.16	-2.936	0.004
SASK IBD	2.10	1.20	3.37	0.96	-4.296	0.000
NATs						
BMI(kg/m^2)	24.10	4.62	21.17	4.29	2.523	0.013
MAC(cm)	26.48	3.34	24.53	3.05	2.331	0.022
Hand Grip Strength(kg)	29.04	9.86	26.16	11.65	1.108	0.271
Triceps Skin Fold Thickness(mm)	13.95	7.30	9.79	6.53	2.280	0.025
Skeletal Muscle Area(cm^2)	103.73	28.16	97.06	23.76	0.659	0.513
SMI(cm^2/m^2)	19.54	20.72	18.62	20.97	0.174	0.862
Hb(g/dL)	10.78	1.40	11.60	1.86	-2.162	0.064
Albumin(g/dL)	3.37	0.43	3.27	0.33	0.923	0.358

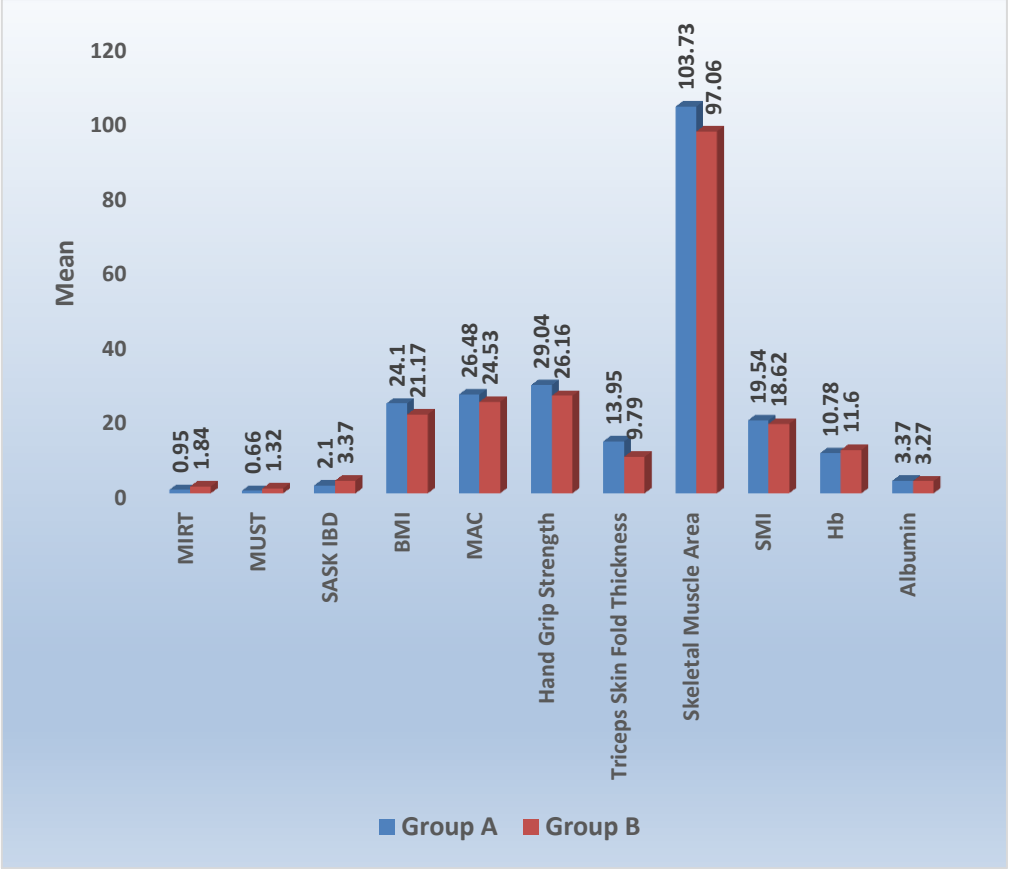


FIGURE 20: COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN UC PATIENTS IN BOTH GROUPS

Crohn's Disease: When screened using nutrition screening tools like MIRT, MUST and SASK IBD, CD patients in Group B were found to be at a significantly higher risk of malnutrition as compared to Group A.

However, nutritional assessment using various NATs in CD in Groups A & B did not reveal any significant difference in the nutritional status of these patients.

TABLE 12B: COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN CD PATIENTS IN BOTH GROUPS

CD	Group A		Group B		Z	p-value
NSTs	Mean	SD	Mean	SD		
MIRT	0.56	0.86	2.67	2.34	-3.330	0.003
MUST	0.50	0.86	1.50	1.38	-2.121	0.045
SASK IBD	1.83	1.25	3.67	1.37	-3.047	0.006
NATs						
BMI(kg/m^2)	24.09	3.79	25.11	6.94	-0.461	0.649
MAC(cm)	27.00	2.97	26.42	3.23	0.408	0.687
Hand Grip Strength(kg)	30.11	11.45	25.33	5.09	0.979	0.338
Triceps Skin Fold Thickness(mm)	14.78	8.39	16.67	10.15	-0.454	0.654
Skeletal Muscle Area(cm^2)	100.08	20.82	97.22	18.55	0.245	0.811
SMI(cm^2/m^2)	14.45	19.10	31.53	16.83	-1.946	0.065
Hb(g/dL)	11.58	2.32	10.38	2.55	1.073	0.295
Albumin(g/dL)	3.51	0.37	3.32	0.61	0.919	0.368

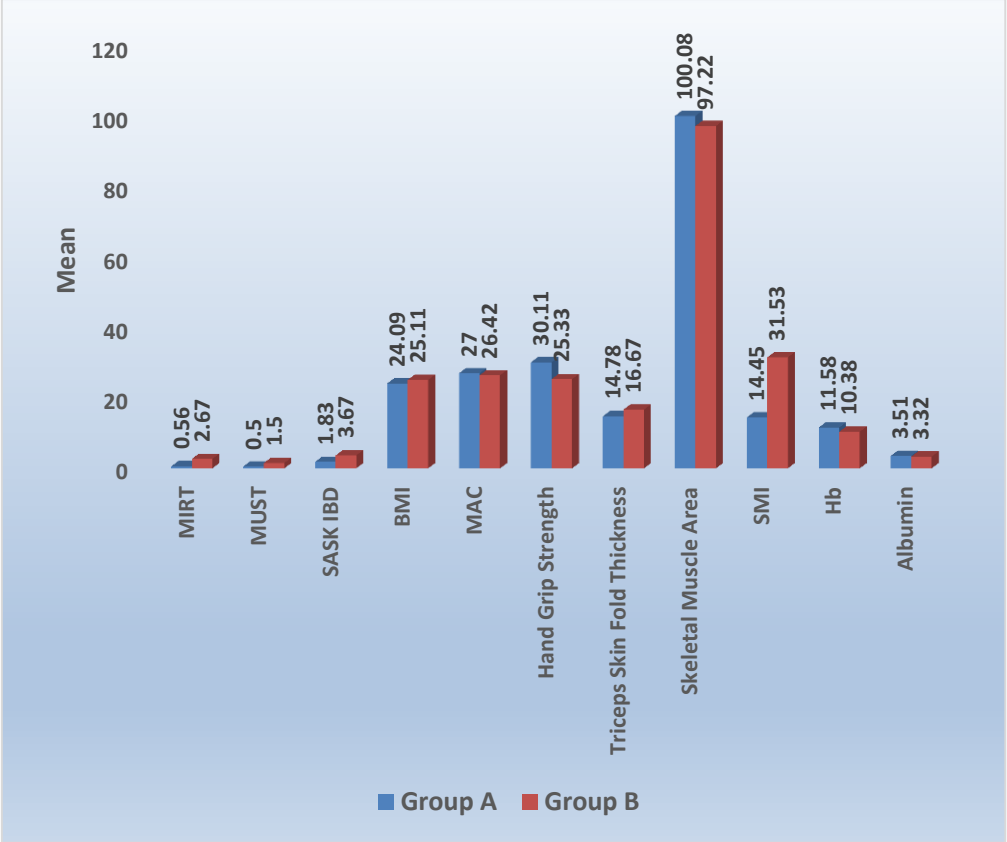


FIGURE 21: COMPARISON OF NUTRITION PARAMETERS AT BASELINE IN CD PATIENTS IN BOTH GROUPS

13. Comparing Duration of disease with Nutrition Parameters:

When screening and assessing the nutritional status according to the disease duration, none of the NSTs & NATs suggested any significant difference in the nutritional status of these patients.

TABLE 13: COMPARING DURATION OF DISEASE WITH NUTRITION PARAMETERS

Duration of Disease	1-5YRS		6-10 YRS		> 11YRS	
NSTs	Mean	SD	Mean	SD	Mean	SD
MIRT	0.80	0.96	1.19	1.17	0.70	0.92
MUST	0.57	0.79	0.85	0.88	0.50	0.76
SASK IBD	2.00	1.24	2.23	1.14	1.95	1.23
NATs						
BMI(kg/m^2)	23.15	4.23	25.54	5.19	25.40	4.98
MAC(cm)	25.82	2.95	27.71	3.60	27.13	3.27
Hand Grip Strength(kg)	31.31	11.50	27.54	7.55	25.80	7.76
Triceps Skin Fold Thickness(mm)	12.70	7.49	16.21	7.67	15.13	6.64
Skeletal Muscle Area(cm^2)	102.46	23.49	102.39	24.67	107.09	41.86
SMI(cm^2/m^2)	14.58	18.78	27.86	18.37	17.55	24.20
Hb(g/dL)	11.10	1.67	10.72	1.82	10.70	1.17
Albumin(g/dL)	3.41	0.41	3.32	0.43	3.47	0.44

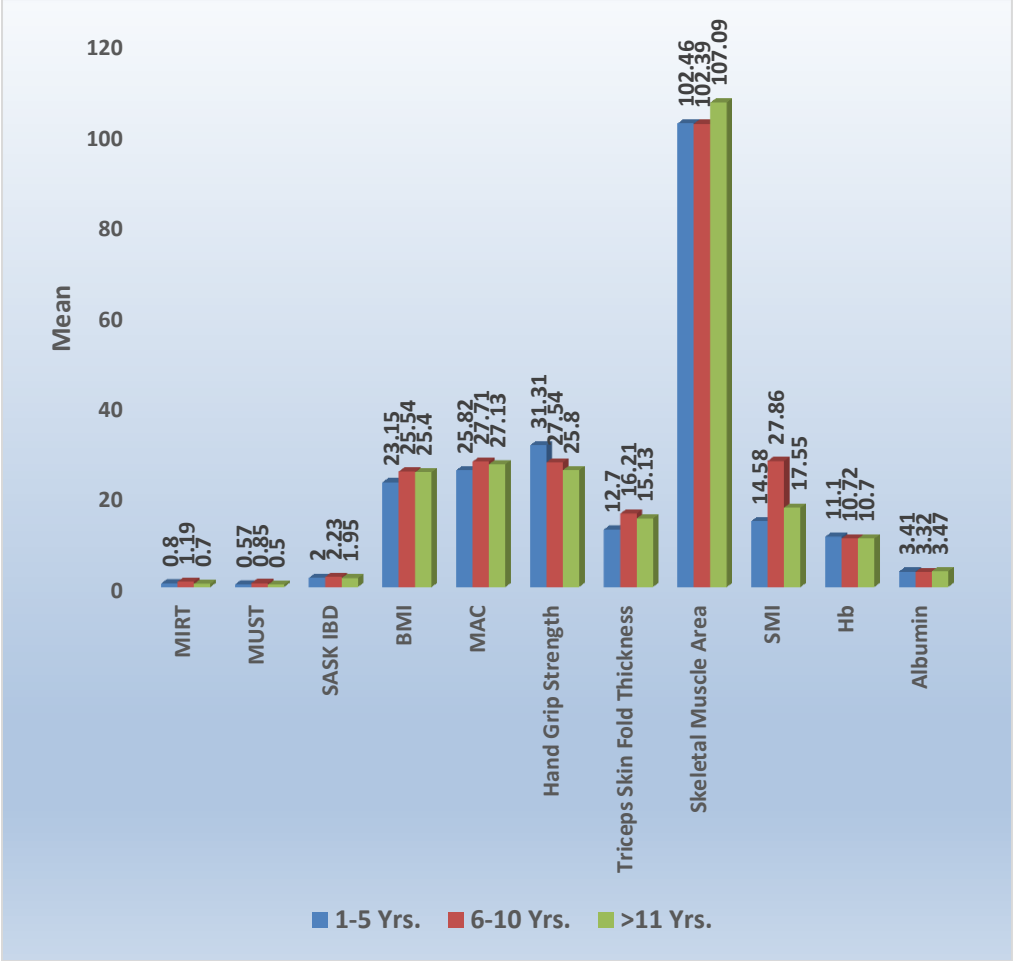


FIGURE 22: COMPARING DURATION OF DISEASE WITH NUTRITION PARAMETERS

14. **Screening for patients at risk for malnutrition using Nutrition Risk Screening tools at baseline: (Table No. 14**)

According to MIRT score a total of 12(9.6%) IBD patients were at risk of malnutrition (defined as MIRT≥3). Four patients were in Group A (4%) and 8 in Group B (32%). As seen in table 14, the risk of malnutrition in both groups was higher in patients with UC (Group A n=4; 100%, Group B n=6; 75%)

According to MUST score a total of 60(48%) IBD patients were at risk of malnutrition (defined as MUST≥1). Forty three patients were in Group A (43%) and 17 (68%) in Group B. As seen in table 14, the risk of malnutrition in both groups was higher in patients with UC (Group A n=38; 88.37%, Group B n=12; 70.59%).

According to SaskIBD score a total of 57(45.6%) IBD patients were at risk of malnutrition (SaskIBD≥3). Thirty seven patients 37 were in Group A (37%) and 20 (80%) in Group B. As seen in table 14, the risk of malnutrition in both groups was higher in patients with UC (Group A n=32; 86.48%, Group B n=15; 75%).

TABLE 14: NUTRITION RISK SCREENING TOOLS AT BASELINE

	Group A					Group B				Total
		UC	CD	Total No. of cases	%age	UC	CD	No. of cases	%age	
MIRT group	0-2	78	18	96	96%	13	4	17	68%	113
	≥3	4	0	4	4%	6	2	8	32%	12
Total				100	100%			25	100%	125

	Group A					Group B				Total
		UC	CD	No. of cases	%age	UC	CD	No. of cases	%age	
MUST group	0	44	13	57	57%	7	1	8	32%	65
	1	23	1	24	24%	2	3	5	20%	29
	≥2	15	4	19	19%	10	2	12	48%	31
Total				100	100%			25	100%	125

	Group A					Group B				Total
		UC	CD	No. of cases	%age	UC	CD	No. of cases	%age	
SASK IBD group	0-2.0	50	13	63	63%	4	1	5	20%	68
	3-4.0	29	5	34	34%	13	4	17	68%	51
	≥5	3	0	3	3%	2	1	3	12%	6
Total				100	100%			25	100%	125

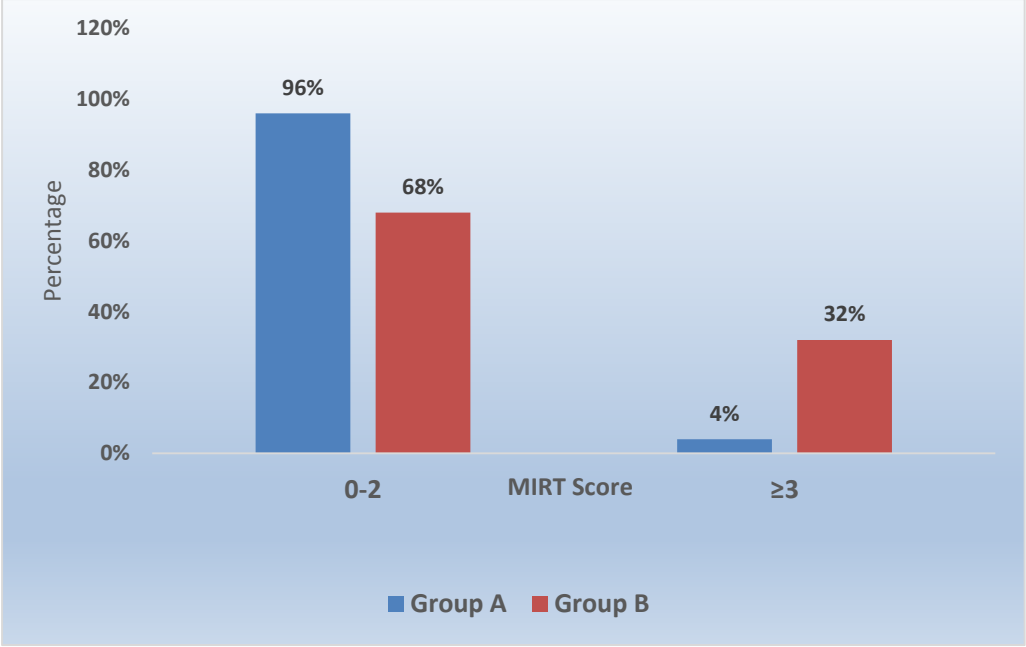


FIGURE 23: MIRT SCORE AT BASELINE

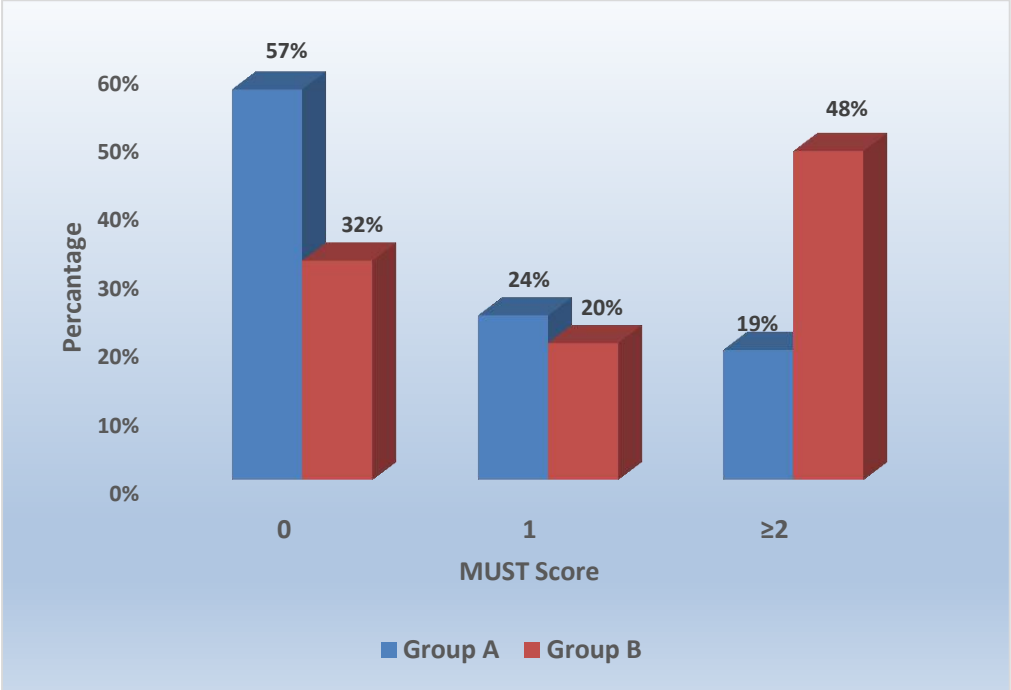


FIGURE 24: MUST SCORE AT BASELINE

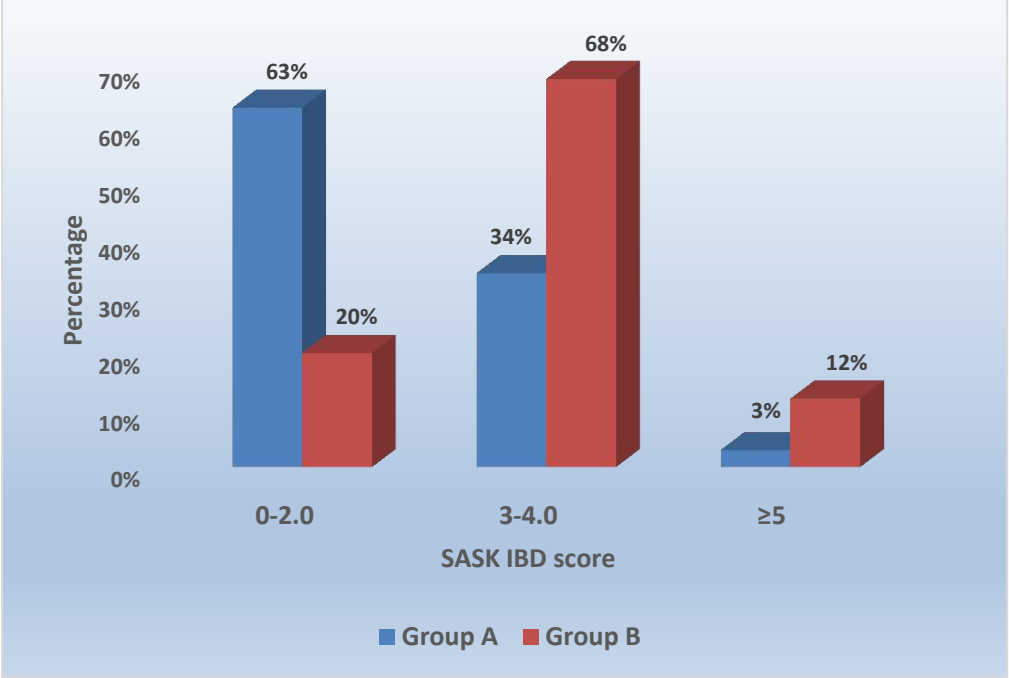


FIGURE 25: SASKIBD SCORE AT BASELINE

15. **Comparing nutrition screening tools with nutrition assessment tools:**

In Group A, when MIRT score was used, patients deemed to be at risk using MIRT had significantly lower BMI. However MAC, Hand Grip Strength, Triceps Skin Fold Thickness, Skeletal Muscle Area SMI, Haemoglobin, Albumin were all comparable.

TABLE 15A: COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

MIRT	0-2.0		≥3		Z	p-value
Group A						
	Mean	SD	Mean	SD		
BMI(kg/m^2)	24.02	4.64	29.00	5.29	-2.092	0.039
MAC(cm)	26.51	3.19	28.00	5.29	-0.889	0.376
Hand Grip Strength(kg)	29.00	9.94	34.75	14.27	-1.116	0.267
Triceps Skin Fold Thickness(mm)	13.82	7.43	20.75	5.74	-1.839	0.069
Skeletal Muscle Area(cm^2)	101.29	25.71	131.82	36.71	-1.947	0.058
SMI(cm^2/m^2)	17.92	20.12	35.48	23.96	-1.698	0.093
Hb(g/dL)	10.91	1.61	11.28	2.11	-0.443	0.659
Albumin(g/dL)	3.41	0.42	3.10	0.37	1.441	0.153

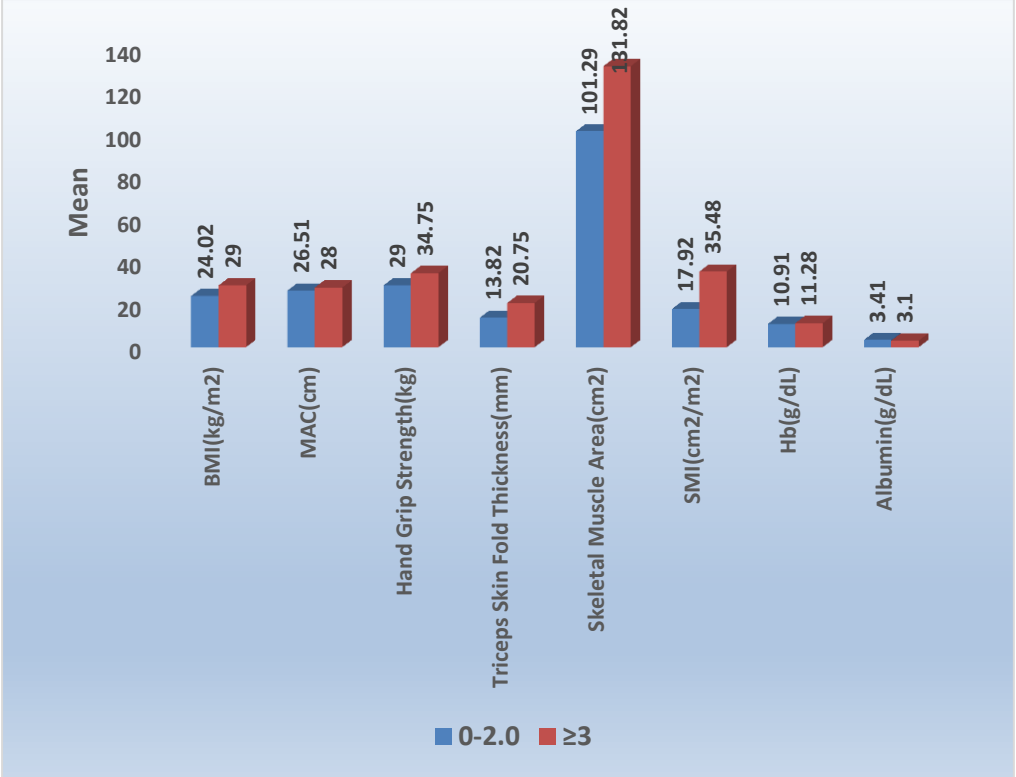


FIGURE 26: COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

In Group B, when MIRT score was used, patients deemed to be at risk using MIRT had significantly lower Haemoglobin. However BMI, MAC, Hand Grip Strength, Triceps Skin Fold Thickness, Skeletal Muscle Area SMI, Albumin were all comparable.

TABLE 15B: COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

MIRT	0-2.0		≥3		Z	p-value
Group B						
	Mean	SD	Mean	SD		
BMI(kg/m^2)	23.24	5.74	20.13	3.14	1.425	0.168
MAC(cm)	25.44	2.73	24.00	3.88	1.075	0.294
Hand Grip Strength(kg)	25.24	10.65	27.50	10.23	-0.502	0.620
Triceps Skin Fold Thickness(mm)	13.41	8.75	7.25	3.11	1.918	0.068
Skeletal Muscle Area(cm^2)	92.12	21.25	106.12	20.32	-1.199	0.254
SMI(cm^2/m^2)	19.88	20.15	25.62	22.10	-0.644	0.526
Hb(g/dL)	11.88	1.82	10.10	2.11	2.165	0.041
Albumin(g/dL)	3.34	0.43	3.16	0.31	1.042	0.308

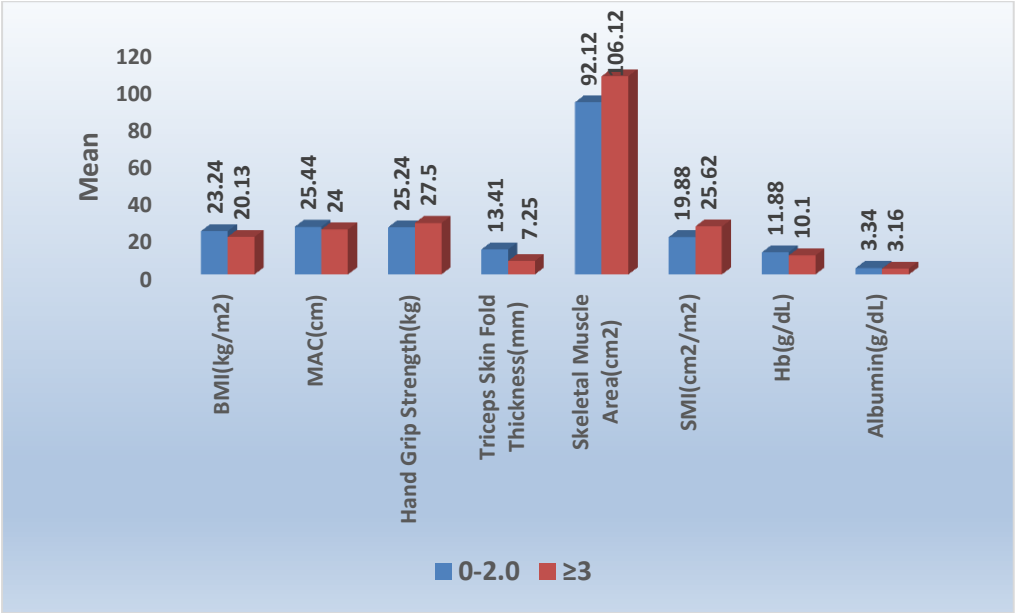


FIGURE 27: COMPARING MIRT GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

In Group A, when MUST score was used, patients deemed to be at risk using MUST had significantly lower BMI and albumin levels. However MAC, Hand Grip Strength, Triceps Skinfold Thickness, Skeletal Muscle Area, SMI and Haemoglobin were all comparable.

TABLE 15C: COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

MUST	0		1		≥2		F	p-value
Group A	Mean	SD	Mean	SD	Mean	SD		
BMI(kg/m^2)	24.96	3.49	24.33	4.78	21.84	6.99	3.238	0.044
MAC(cm)	27.01	2.55	26.55	3.35	25.30	4.70	1.983	0.143
Hand Grip Strength(kg)	28.25	10.97	28.46	7.47	33.16	9.79	1.803	0.170
Triceps Skin Fold Thickness(mm)	15.38	7.26	13.65	6.88	10.84	8.11	2.780	0.067
Skeletal Muscle Area(cm^2)	96.80	20.56	111.72	23.50	109.15	36.86	1.516	0.231
SMI(cm^2/m^2)	16.77	19.68	15.18	20.25	28.56	20.94	2.932	0.058
Hb(g/dL)	11.16	1.62	10.58	1.36	10.65	1.87	1.448	0.240
Albumin(g/dL)	3.59	0.35	3.21	0.34	3.04	0.39	21.886	0.000

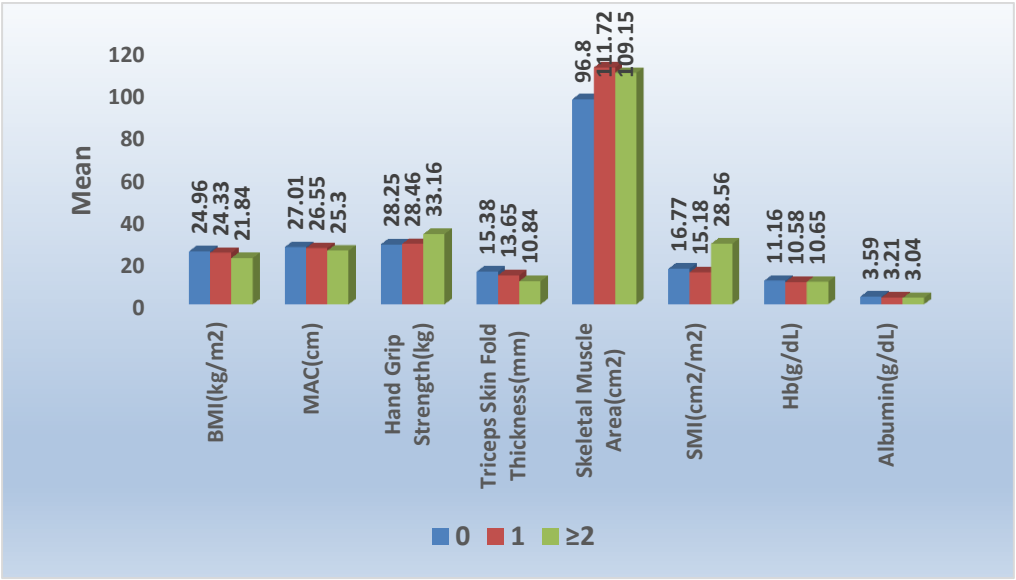


FIGURE 28: COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

In Group B, when MUST score was used, patients deemed to be at risk using MUST had significantly lower BMI and MAC. However Hand Grip Strength, Triceps Skinfold Thickness, Skeletal Muscle Area, SMI, Haemoglobin and Albumin levels were all comparable.

TABLE 15D: COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

MUST	0		1		≥2		F	p-value
Group B	Mean	SD	Mean	SD	Mean	SD		
BMI(kg/m^2)	26.50	6.09	22.20	3.56	19.42	2.97	6.498	0.006
MAC(cm)	26.94	1.45	25.60	3.13	23.42	3.31	3.906	0.035
Hand Grip Strength(kg)	29.00	13.05	27.00	3.54	23.50	10.36	0.690	0.512
Triceps Skin Fold Thickness(mm)	15.88	8.44	12.80	10.66	7.92	4.56	2.935	0.074
Skeletal Muscle Area(cm^2)	102.53	18.78	83.07	15.00	97.27	24.89	0.556	0.589
SMI(cm^2/m^2)	25.80	21.78	13.10	18.56	22.59	21.07	0.590	0.563
Hb(g/dL)	12.41	1.64	11.02	2.21	10.69	2.09	1.870	0.178
Albumin(g/dL)	3.54	0.48	3.06	0.27	3.21	0.32	3.037	0.068

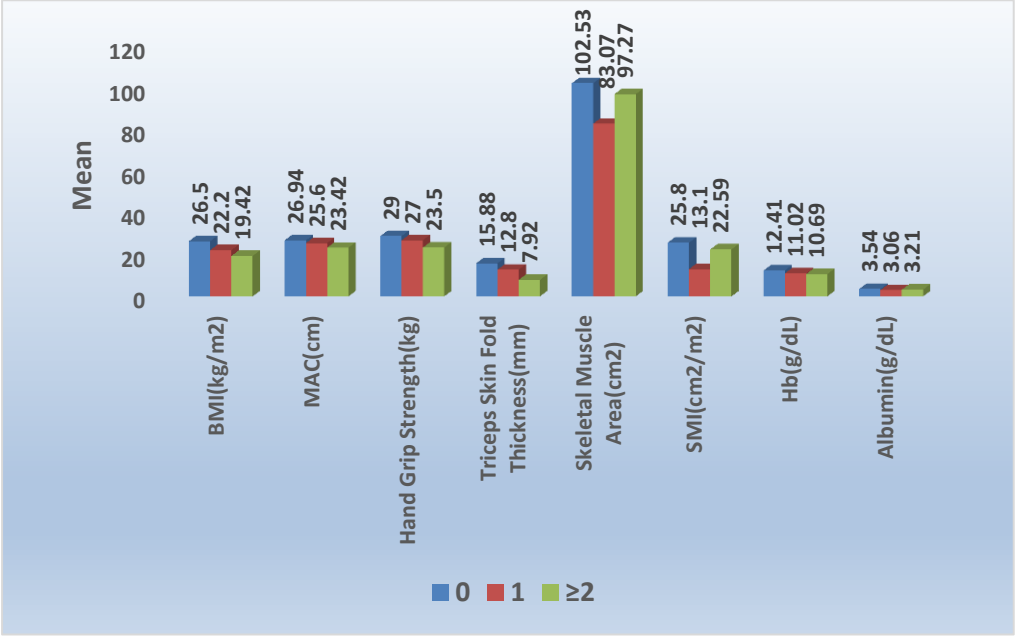


FIGURE 29: COMPARING MUST GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

In group A, when SASK IBD score was used, patients deemed to be at risk using SASK IBD had significantly lower albumin levels. However BMI, MAC, Hand Grip Strength, Triceps Skinfold Thickness, Skeletal Muscle Area, SMI and Haemoglobin were all comparable.

TABLE 15E: COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

SASKIBD	0-2.0		3-4.0		≥5		F	p-value
Group A	Mean	SD	Mean	SD	Mean	SD		
BMI(kg/m^2)	24.79	4.41	22.91	4.41	27.00	11.79	2.330	0.103
MAC(cm)	26.92	2.74	25.96	3.89	26.33	6.11	0.947	0.392
Hand Grip Strength(kg)	28.40	9.50	30.09	10.64	37.00	16.46	1.228	0.297
Triceps Skin Fold Thickness(mm)	14.45	6.99	13.46	8.39	14.00	8.72	0.193	0.824
Skeletal Muscle Area(cm^2)	97.04	19.48	104.58	27.78	105.23	21.43	1.965	0.435
SMI(cm^2/m^2)	15.71	19.26	22.17	20.26	28.58	35.74	1.328	0.178
Hb(g/dL)	11.10	1.64	10.66	1.49	10.00	2.65	1.322	0.271
Albumin(g/dL)	3.53	0.38	3.17	0.38	3.10	0.61	10.864	0.000

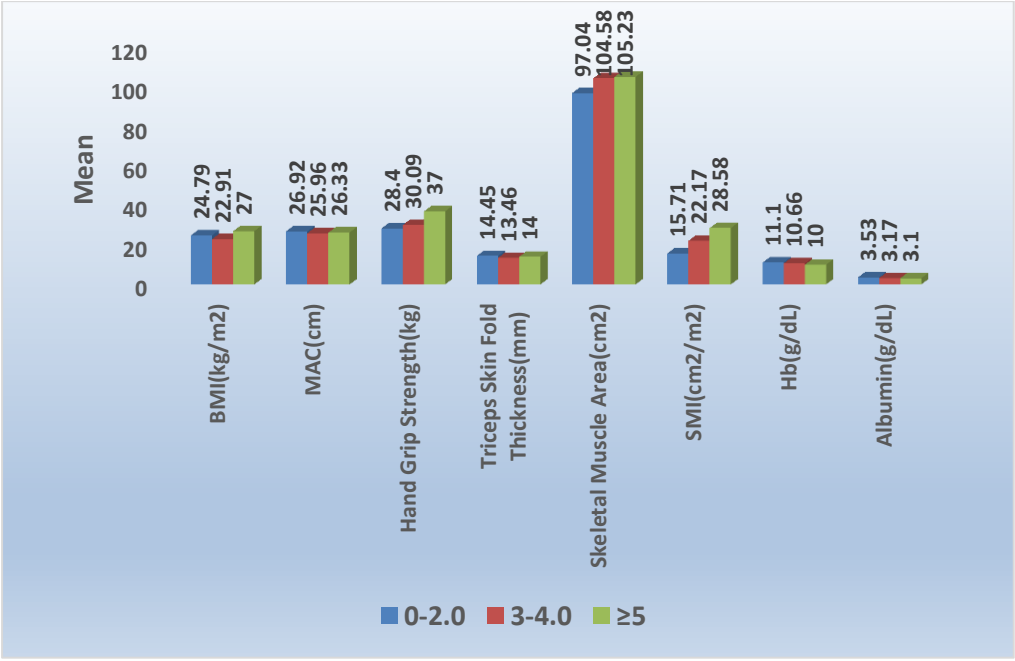


FIGURE 30: COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP A

In group B, when SASK IBD score was used, patients deemed to be at risk using SASK IBD had significantly lower BMI, MAC and haemoglobin levels. However Hand Grip Strength, Triceps Skinfold Thickness, Skeletal Muscle Area, SMI and Albumin were all comparable.

TABLE 15F: COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

SASKIBD	0-2.0		3-4.0		≥5		F	p-value
Group B	Mean	SD	Mean	SD	Mean	SD		
BMI(kg/m^2)	28.00	6.63	21.18	3.91	18.67	1.53	5.781	0.010
MAC(cm)	27.70	1.10	24.74	3.16	21.83	1.44	4.420	0.024
Hand Grip Strength(kg)	34.80	12.30	23.00	9.09	28.00	6.93	3.003	0.070
Triceps Skin Fold Thickness(mm)	17.20	7.85	10.82	7.76	5.33	1.53	2.575	0.099
Skeletal Muscle Area(cm^2)	113.52	15.58	87.31	19.49	106.89	21.01	2.545	0.124
SMI(cm^2/m^2)	26.56	24.49	16.96	19.14	40.61	11.42	2.029	0.155
Hb(g/dL)	13.14	1.43	11.12	1.87	9.30	2.00	4.504	0.023
Albumin(g/dL)	3.60	0.61	3.22	0.28	3.13	0.47	2.200	0.135

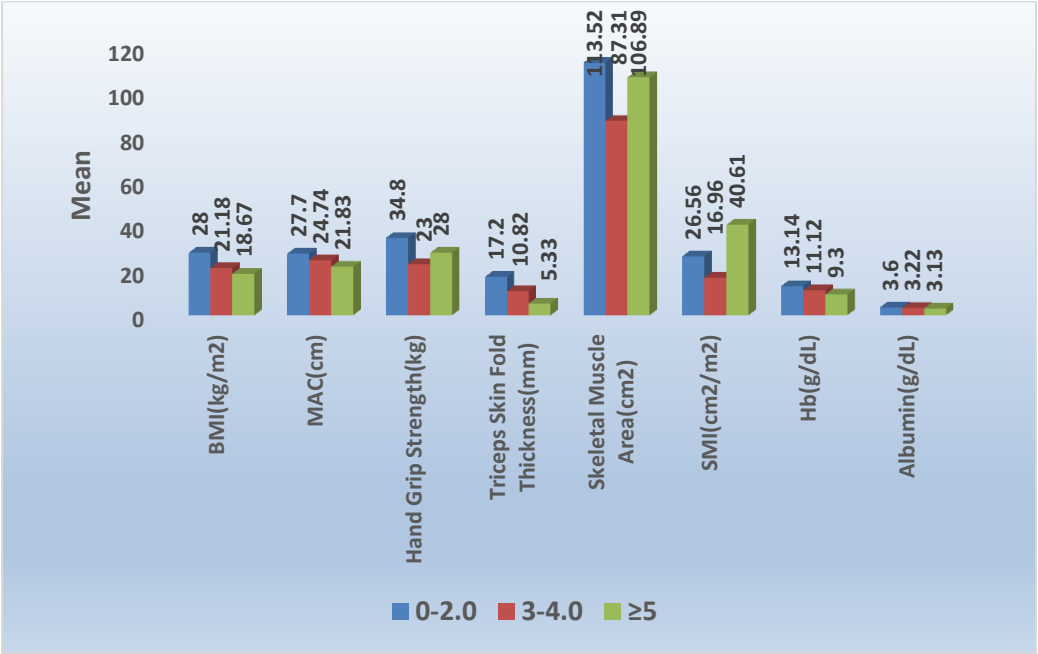


FIGURE 31: COMPARING SASKIBD GROUPS WITH NUTRITION ASSESSMENT TOOLS IN GROUP B

16. **Outcomes:** In Group A during follow up, 3 patients were lost to follow up at the start of the study and 9 were lost to further follow up after 6 months. Out of the remaining 88 patients, 72 (81.82%) remained in remission, 16 (18.18%) had of relapse, 4 (4.54%) among them had to be hospitalised and treated with intravenous steroids and antibiotics. No patient in Group A had to undergo surgery or had any mortality on follow up.

    In Group B during follow up, 3 patients were lost to follow up at the start of the study and 3 were lost to further follow up after 6 months. Out of the remaining 19 patients, disease went into remission in 17 patients, disease remained active in 2 patients at 1 year even after dose escalation. Among 17 patients that went in remission, 3 had an episode of relapse during follow up requiring a course of antibiotics and dose escalation. No patient in Group B had to undergo surgery or had any mortality on follow up.

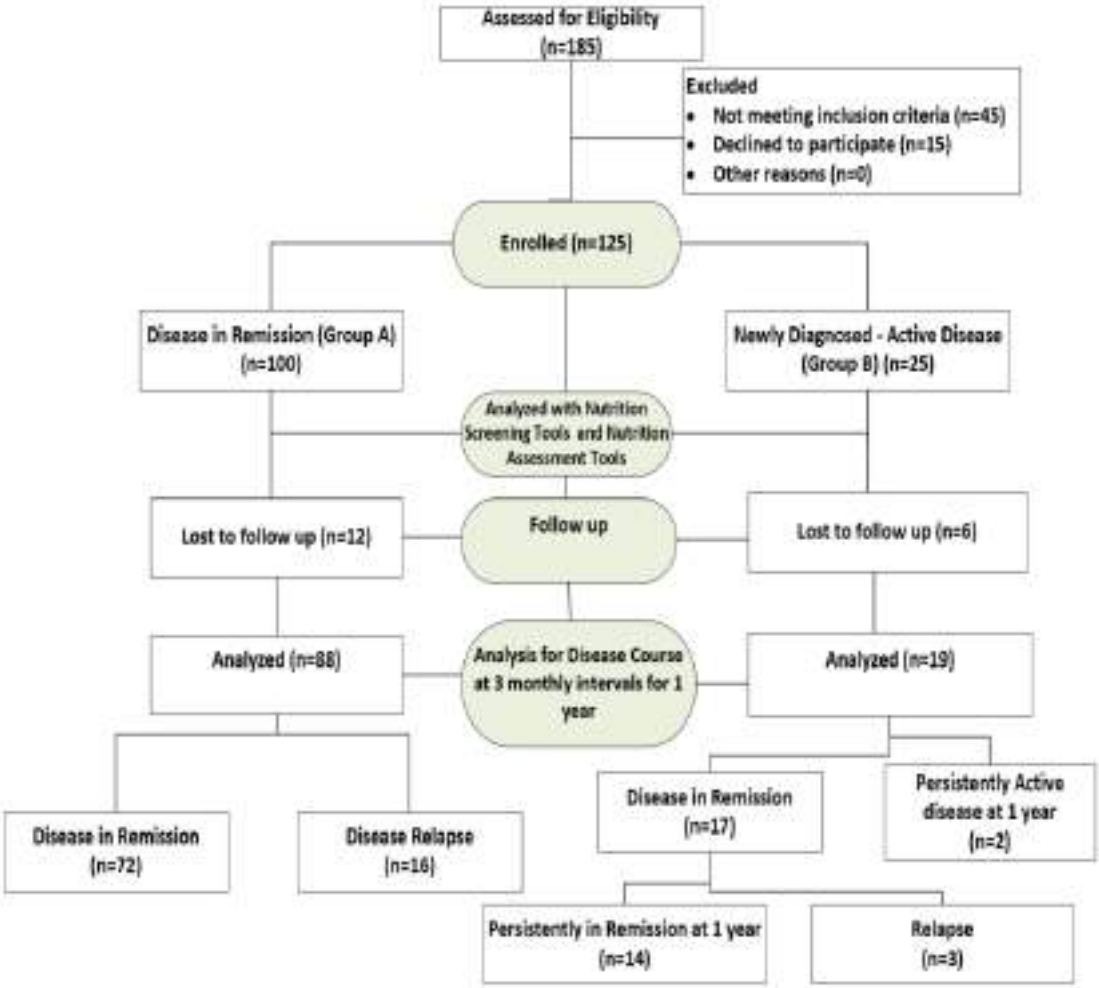

Assessed for Eligibility (n=185)
Excluded
Not meeting inclusion criteria (n=45)
Declined to participate (n=15)
Other reasons (n=0)
Enrolled (n=125)
Disease in Remission (Group A) (n=100)
Newly Diagnosed - Active Disease (Group B) (n=25)
Analyzed with Nutrition Screening Tools and Nutrition Assessment Tools
Lost to follow up (n=12)
Follow up
Lost to follow up (n=6)
Analyzed (n=88)
Analysis for Disease Course at 3 monthly intervals for 1 year
Analyzed (n=19)
Disease in Remission (n=72)
Disease Relapse (n=16)
Disease in Remission (n=17)
Persistently Active disease at 1 year (n=2)
Persistently in Remission at 1 year (n=14)
Relapse (n=3)

FIGURE 32: OUTCOMES DURING FOLLOW UP

17. **Baseline parameters of patients, who remained in remission versus those who relapsed during follow up:** In Group A, when comparing nutritional screening parameters between patients who remained in remission versus those who relapsed on follow up, MUST and SASK IBD had significant associations with p value <0.05. Patients who relapsed had higher mean values of MUST and SASK IBD score than those who remained in remission. MIRT score, although higher in patients with relapse, but the difference failed to reach statistical significance.

    In Group A, the nutritional status in patients, who remained in remission was similar to those who relapsed, using various NATs. However, patients who relapsed had lower mean value of albumin then those who remained in remission (p<0.05).

TABLE 16A: COMPARISON OF BASELINE PARAMETERS OF THOSE WHO REMAINED IN REMISSION VERSUS THOSE WHO RELAPSED ON FOLLOW UP IN GROUP A

Disease Activity Group A	**Remission**		**Active**			
NSTs	Mean	SD	Mean	SD	Z	p-value
MIRT	0.75	0.92	1.19	1.11	-1.663	0.100
MUST	0.50	0.69	1.13	1.02	-2.973	0.004
SASK IBD	1.81	1.06	3.13	1.02	-4.542	0.000
NATs						
BMI(kg/m^2)	24.24	4.18	24.00	7.22	0.176	0.861
MAC(cm)	26.49	2.86	27.05	4.54	-0.632	0.529
Hand Grip Strength(kg)	29.31	9.75	28.88	9.86	0.160	0.874
Triceps Skin Fold Thickness(mm)	14.40	7.25	12.63	9.86	0.828	0.410
Skeletal Muscle Area(cm^2)	100.16	23.83	105.38	32.63	-0.557	0.580
SMI(cm^2/m^2)	26.14	18.99	28.00	22.79	-2.361	0.520
Hb(g/dL)	10.95	1.61	10.39	1.60	1.266	0.209
Albumin(g/dL)	3.44	0.39	3.20	0.54	2.058	0.043

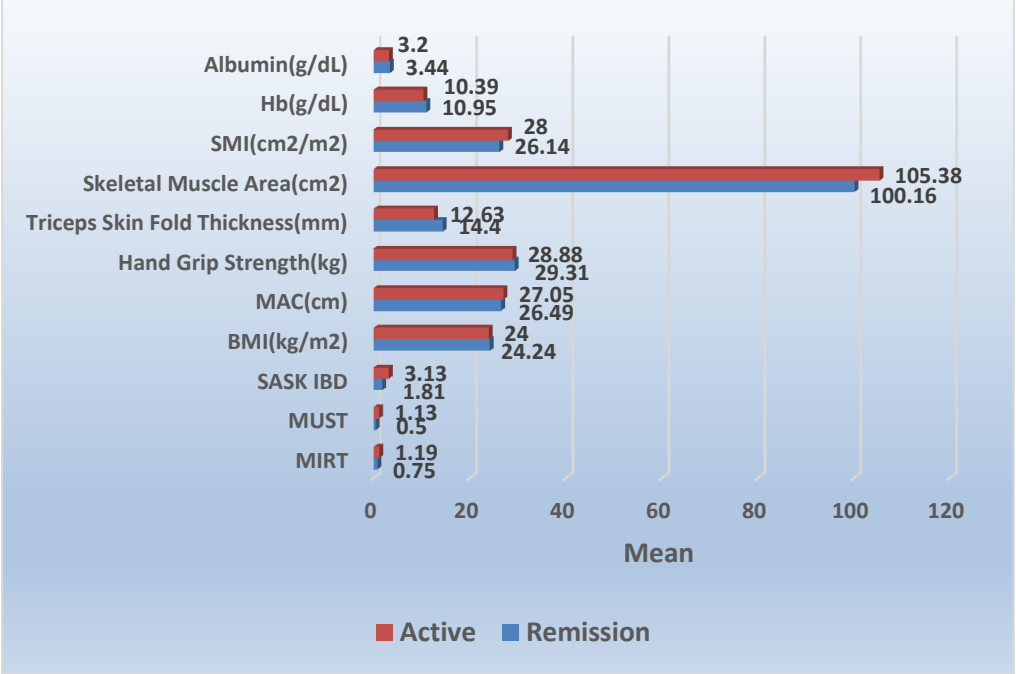


FIGURE 33: COMPARISON OF BASELINE PARAMETERS OF THOSE WHO REMAINED IN REMISSION VERSUS THOSE WHO RELAPSED ON FOLLOW UP IN GROUP A

In Group B, all three NSTs (MIRT, MUST, SaskIBD) suggested higher risk of malnutrition in patients who failed to achieve remission or relapsed after achieving remission at 1 year when compared to those who achieved remission, however the differences were not statistically significant (Table 16B). Among the NATs, lower albumin levels at baseline significantly correlated with negative clinical outcomes (active disease/relapse after initial response). Other NATs were comparable in patients who achieved remission versus those who relapsed.

In Group B, when comparing nutritional assessment parameters between patients who achieved remission and continued to be in remission at 1 year with those who failed to achieve remission or relapsed after achieving remission at 1 year, albumin levels had significant association with p value <0.05. Patients who relapsed had lower mean value of albumin than those who remained in remission.

TABLE 16B: COMPARISON OF BASELINE PARAMETERS OF THOSE WHO ACHIEVED REMISSION VERSUS THOSE WHO REMAINED ACTIVE OR RELAPSED ON FOLLOW UP IN GROUP B

Disease Activity Group B	Remission		Active/Relapse			
NSTs	Mean	SD	Mean	SD	Z	p-value
MIRT	1.57	1.34	3.40	2.19	-1.707	0.088
MUST	1.00	1.11	2.20	1.30	-1.741	0.082
SASK IBD	3.14	0.95	4.20	1.30	-1.589	0.112
NATs						
BMI(kg/m^2)	23.43	6.16	20.40	4.51	-1.212	0.225
MAC(cm)	25.54	3.17	23.50	3.28	-1.259	0.208
Hand Grip Strength(kg)	24.50	10.97	24.60	9.10	-0.371	0.711
Triceps Skin Fold Thickness(mm)	13.71	7.63	8.00	10.12	-1.948	0.051
Skeletal Muscle Area(cm^2)	97.46	22.16	85.07	19.39	-0.189	0.850
SMI(cm^2/m^2)	20.45	22.13	26.42	15.77	-0.240	0.810
Hb(g/dL)	11.77	1.37	10.84	2.63	-0.557	0.578
Albumin(g/dL)	3.36	0.40	2.96	0.26	-2.051	0.040

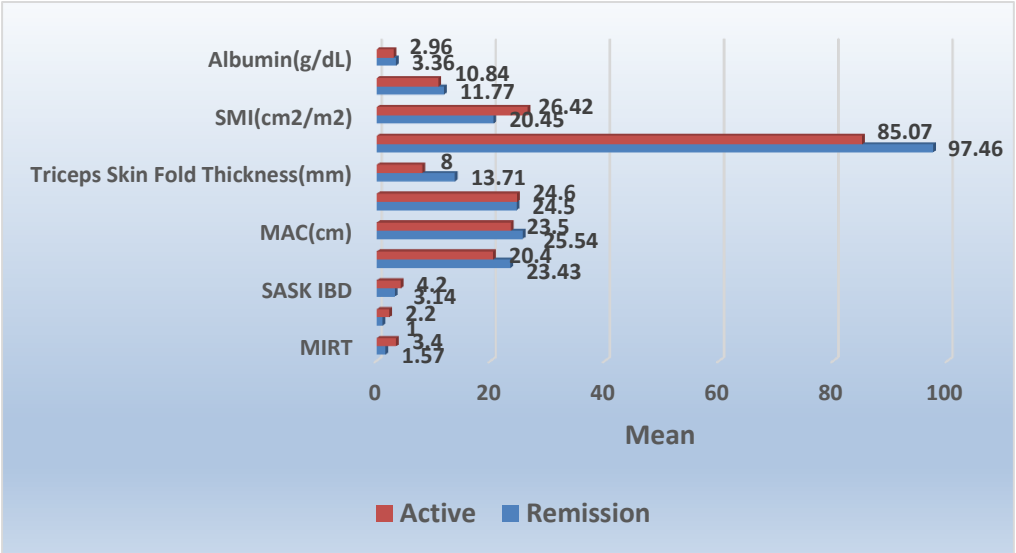


FIGURE 34: COMPARISON OF BASELINE PARAMETERS OF THOSE WHO ACHIEVED REMISSION VERSUS THOSE WHO REMAINED ACTIVE OR RELAPSED ON FOLLOW UP IN GROUP B

18. **Impact of baseline Nutritional Screening Tools on outcomes during follow up:** A total of 12 patients were lost to follow up in Group A. So outcomes were calculated in the remaining 88 patients.

    Using MIRT score, 86 patients were in low risk MIRT category with score of 0-2 while 2 patients were in high risk category with score ≥3 at baseline. During follow up, in low risk category, 15 (17.4%) patients had an episode of relapse whereas in high risk category, 1 (50%) patient had an episode of relapse. The difference in clinical outcomes in both these groups was statistically insignificant (p=0.265).

    Using MUST score, 51 patients were in low risk category with score of 0 while 37 patients were in moderate to high risk category with score ≥1 at baseline. During follow up, in low risk category, 7 (13.7%) patients had an episode of relapse whereas in high risk category, 9 (24.3%) patients had an episode of relapse. The difference in clinical outcomes in both these groups was statistically insignificant (p=0.265).

    Using SaskIBD score, 56 patients were in low risk category with score of 0-2 while 32 patients were in moderate to high risk category with score ≥3 at baseline. During follow up, in low risk category, 5 (8.9%) patients had an episode of relapse whereas in moderate to high risk category, 11 (34.4%) patients had an episode of relapse. The difference in clinical outcomes in both these groups was statistically significant (p=0.004).

TABLE 17A: IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP A

		Disease Activity				Total	Chi-square value	p-value
		Remission		Active				
MIRT	0-2	71	82.60%	15	17.40%	86	1.393	0.332
	≥3	1	50.00%	1	50.00%	2		
MUST	**0**	**44**	**86.3%**	**7**	**13.7%**	**51**	**1.619**	**0.265**
	≥1	**28**	**75.7%**	**9**	**24.3%**	**37**		
SaskIBD	0-2	51	91.10%	5	8.90%	56	8.864	0.004
	≥3	21	65.60%	11	34.40%	32		

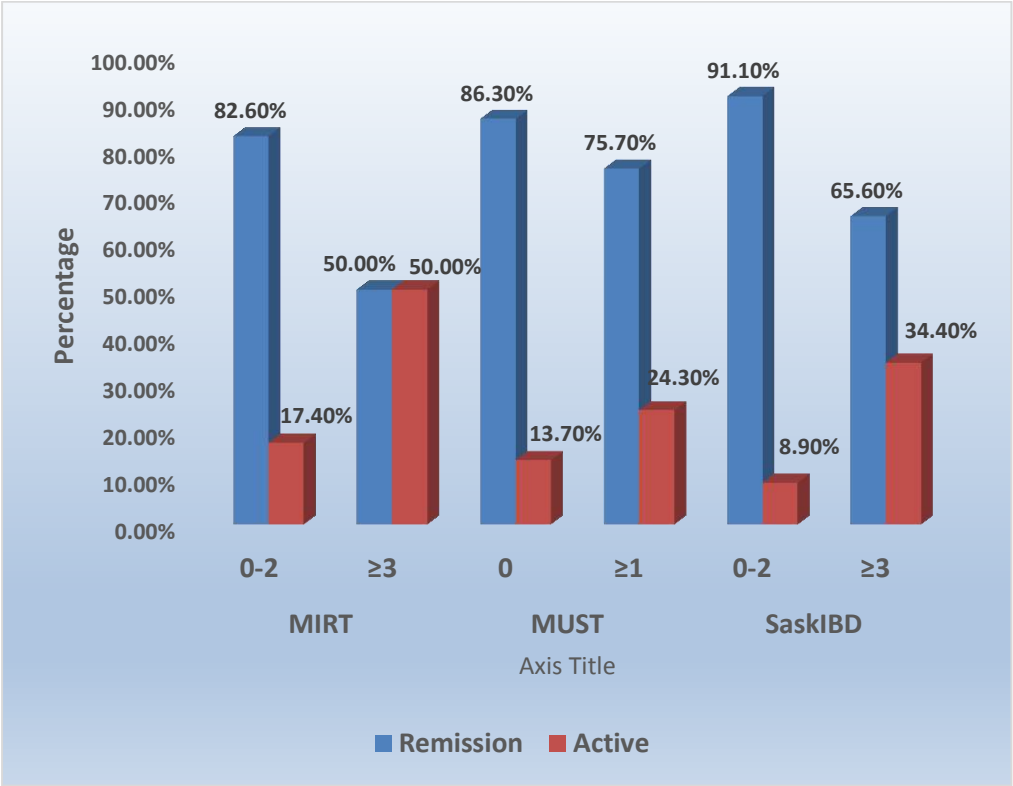


FIGURE 35: IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP A

A total of 6 patients were lost to follow up in Group B. Clinical outcomes of the remaining 19 patients were assessed at 1 year of follow up.

Using MIRT score, 13 patients were in low risk category with score of 0-2 while 6 patients were in high risk category with score ≥3 at baseline. During follow up, in low risk category, 3 (23%) patients had persistently active disease or an episode of relapse whereas in high risk category, 2 (33%) patients had persistently active disease or an episode of relapse. The difference in clinical outcomes in both these groups was statistically insignificant (p=0.637).

Using MUST score, 7 patients were in low risk category with score of 0 while 12 patients were in moderate to high risk category with score ≥1 at baseline. During follow up, in low risk category, no (0%) patient had persistently active disease or an episode of relapse whereas in moderate to high risk category, 5 (42%) patients had persistently active disease or an episode of relapse. The difference in clinical outcomes in both these groups was statistically insignificant (p=0.106).

Using the SaskIBD score, 4 patients were in low risk category with score of 0-2 while 15 patients were in moderate to high risk category with score ≥3 at baseline. During follow up, in low risk category, no patient had persistently active disease or an episode of relapse whereas in moderate to high risk category, 5 (33%) patients had persistently active disease or an episode of relapse. The difference in clinical outcomes in both these groups was statistically insignificant (p=0.53).

TABLE 17B: IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP B

		Disease Activity				Total	Chi-square value	p-value
		Remission		Active/Relapse				
MIRT	0-2	10	77%	3	23%	13	0.223	0.637
	≥3	4	67%	2	33%	6		
MUST	**0**	**7**	**100%**	**0**	**0%**	**7**	**3.958**	**0.106**
	≥1	**7**	**58%**	**5**	**42%**	**12**		
SaskIBD	0-2	4	100%	0	0%	4	1.81	0.53
	≥3	10	67%	5	33%	15		

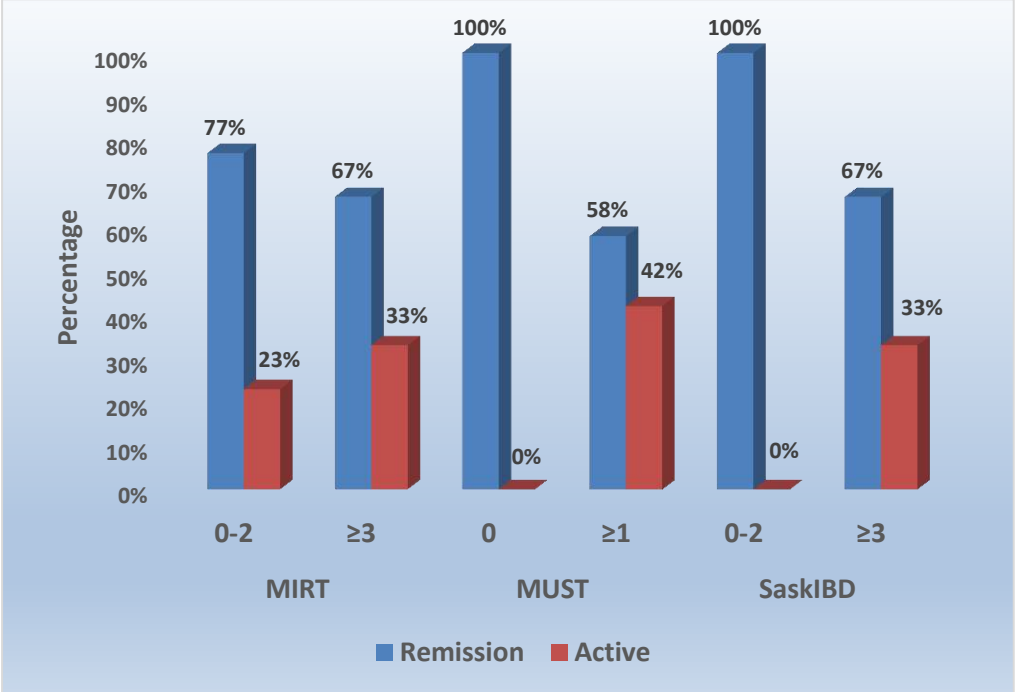


FIGURE 36: IMPACT OF BASELINE NUTRITION SCREENING TOOLS ON PATIENT OUTCOMES IN GROUP B

DISCUSSION

This study was conducted on the patients attending the outpatient department in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India. One hundred and twenty-five patients were enrolled during the study period. Of these, 100 were those who were already diagnosed with IBD and were in remission (Group A) and 25 were newly diagnosed IBD patients (Group B). All patients enrolled in the study were initially screened using Nutrition Screening Tools: MIRT, MUST and SASK IBD. Thereafter, all these patients also underwent a detailed assessment for the nutritional status using Nutrition Assessment Tools: anthropometric data, handgrip strength, CT MSI (If available), haemoglobin and albumin levels. Patients were followed-up for the clinical course of disease at 3 monthly intervals till 1 year in person and clinical outcomes like maintenance/attainment of remission, disease flare-ups, hospitalisations, surgery and death/mortality were assessed.

There is limited evidence correlating NSTs, NATs and clinical outcomes in IBD. Although some studies support the association of NSTs/NATs with specific clinical outcomes, the heterogeneity in study design, lack of data from large cohorts, and lack of comprehensive validation of existing NSTs, does not translate into the recommendation of a single optimal NST or NAT at this time. The high prevalence of malnutrition seen across various studies reaffirms the ongoing significance of malnutrition in the IBD population and the need to utilize appropriate NST/NATs. Consistent with guideline recommendations, nutrition screening should be conducted on every patient with IBD both at diagnosis and at least annually, with more frequent measures as needed. Referral should be made to a registered dietician in patients at moderate or high risk of malnutrition for more definitive assessment.

Mean age of patients in our study was 40.27±13.23 years (Group A 40.46±13.13, Group B 39.52±13.90, p=0.736). A majority of patients were in the 30-50 age group in both groups A and B. The mean age of

UC patients in our study was 39.58±13.26 years (Group A 40.39±13.09, Group B 36.11±13.78: p=0.206). The mean age of CD patients in our study was 43.17±13.01 years (Group A 40.78±13.69, Group B 50.33±7.74: p=0.122). In a country-wide survey of IBD from India, the mean age at diagnosis of UC and CD was 38.5 and 35.9 years, respectively[73]. The difference in mean age of newly diagnosed (Group B) CD patients in our study from the previous study could be due to low prevalence of CD in Northern India and lower number of CD patients in Group B (n=6).

UC (n=101, 80.8%) was more common than CD (n=24, 19.2%), with a UC:CD ratio of 4.2:1 (Group A UC:CD=4.5:1, Group B UC:CD=3.1:1). In previous studies from Asia, it has been observed that the burden of UC is twice that of CD in Asia as compared to the West[74-76]. In the ACCESS study, the incidence and prevalence of UC was twice that of CD in the included Asian countries, whereas in Australia a reverse ratio was observed[77]. Epidemiological studies from Western countries have shown that the increase in the incidence of UC precedes the increase in that of CD by about 15–20 years which could be the reason of higher number of UC patients in our study[78].

Mean BMI of patients in the study was 23.82±4.88 kg/m^2 (Group A 24.22±4.74, Group B 22.24±5.20:p=0.018). Similar BMI values were obtained in studies by Jansen et al, Knappe-Drzikova et al and Pizzoferrato et al in IBD patients.[59,65,66] In a study by Ghoshal from northern India in 2008, the mean BMI of IBD patients was 19.8(13.7-27.5) kg/m^2[7].

Twelve percent of patients in our study were underweight (Group A 11%, Group B 16%), 33.6% patients were overweight (Group A 39%, Group B 12%) and 16.8% patients were obese (Group A 17%, Group B 16%). The higher BMI in our study reflects the rising prevalence of obesity in Indian population in the last decade.

Studies from other parts of world have shown a similar trend, with obesity in 15–40% of adults and 20–40% patients being overweight[80-

[82]. In a population-based study of 489 patients with IBD conducted in Scotland, 18% of patients were obese (compared with 23% of the general population), and 38% of patients were overweight; this proportion was comparable between patients with Crohn's disease (18% obese) or ulcerative colitis (17.5% obese)[83]. The difference of mean BMI between the 2 groups in our study was significant with lower mean value in patients with active disease which was similar to the study by Ghoshal[7].

Mean MAC of patients in the study was 26.26±3.30 cm (Group A 26.57±3.27, Group B 24.98±3.14: p=0.032). The difference between the mean values between the two groups was significant with p value <0.05. This was similar to the study done by Back et al and Ghoshal where the difference in mean values between active disease and disease in remission was statistically significant[7,79].

Mean triceps skin fold thickness of patients in the study was 13.57±7.60 mm (Group A 14.10±7.47, Group B 11.44±7.90: p=0.071). Although patients in Group A had more triceps skin fold thickness than patients in Group B indicating that patients in active disease were more prone to malnourishment, but the difference failed to reach statistical significance. This result was similar to the study done by Back et al where although the patients with active disease had lower mean TSFT values, but the difference was not significant[79].

Mean hand grip strength of patients in the study was 28.58±10.20 kg (Group A 29.23±10.11, Group B 25.96±10.36: p=0.189). Although patients in Group A had more hand grip strength than patients in Group B but the difference failed to reach statistical significance. In a study by Ze Lan Lu et al in patients of CD, handgrip strength and handgrip strength index were significantly decreased in the group of CD patients compared with controls reflecting sarcopenia[69].

CRP is the most widely used serum indicator of inflammation in IBD. Increased levels of CRP help differentiate mucosal active disease from quiescent IBD. Mean CRP of patients in the study was 5.97±8.67 mg/L

(Group A 3.98±4.96, Group B 13.95±14.29: p=0.001). The difference between the mean values between the two groups was statistically significant. A study by Solem et al showed similar results and proved that endoscopic disease activity correlates well with the serum CRP level and patients with active disease have more CRP than patients in remission[84]. A study by Vermeire et al showed that in CD, serum levels of CRP correlate well with disease activity and with other markers of inflammation[85].

Mean albumin levels of patients in our study were3.37±0.42 g/dL (Group A 3.40±0.42, Group B 3.28±0.40: p=0.178). Although patients in Group A had more average albumin levels than patients in Group B but the difference failed to reach statistical significance. A study by Khan et al showed that hypoalbuminemia at disease diagnosis can serve as a prognostic marker to predict the clinical course of UC at the time of diagnosis and showed that patients with hypoalbuminemia at diagnosis had a higher likelihood of ≥ 2 courses of steroid use (adjusted HR = 1.7, 95%CI: 1.3-2.3), higher likelihood of thiopurine or anti- TNF use (adjusted HR = 1.72, 95%CI: 1.23-2.40) than patients with normal albumin level at diagnosis.[86] Similar results were obtained in our study as the difference between mean albumin levels in patients who remained in remission versus those who had an episode of relapse during follow up (Remission 3.44±0.39, Relapse 3.20±0.54; p=0.043) was statistically significant.

When compared, there was no significant difference in the nutrional status of patients with UC and CD in our patients. This is in contrast to the study done by Back et al where patients with CD had more severe abnormalities in anthropometric parameters than UC patients.[79]This may be because of two reasons: The patients in Group A being in remission at baseline and small number of CD patients in Group B (n=6).

When screened using nutrition screening tools like MIRT, MUST and SASK IBD, patients with IBD in remission had significantly lesser risk of

malnutrition and better clinical outcomes. These NSTs suggested significantly higher risk of malnutrition in patients with active disease as compared to those in remission at the time of recruitment. On detailed assessment using NATs, patients with active disease were found to have significantly lower BMI, MAC and Triceps Skinfold Thickness, while Hand Grip Strength, Skeletal Muscle Area, Haemoglobin and Albumin were comparable between the 2 groups. This was similar to the study by Back et al where BMI, MAC and TSFT showed significant difference between patients that were in remission versus those who had active disease[79]. When comparing CD patients with active disease and those in remission, MIRT, MUST, SASK IBD showed significant difference with $p < 0.05$. However, none of the nutrition assessment tools showed any statistically significant difference between active and in remission CD patients. This may be due to the small sample size of CD patients with active disease (n=6).

According to MIRT score at baseline, 4%(n=4: UC=4,CD=0) of patients in Group A and 32%(n=8:UC=6,CD=2) of patients in Group B were at risk of malnutrition (MIRT≥3).In the study by Jansen et al in patients of CD in remission, 16.4% of patients had MIRT score of ≥3.[59] This may be related to higher mean values of CRP levels in CD patients in that study (CRP 8.1±15.1) as compared to ours (Group A 3.98±4.96, Group B 13.95±14.29). As CRP is one of the components of MIRT score, this may have led to higher mean score of MIRT in that study.

According to MUST score at baseline, 24% (n=24: UC=23,CD=1) of patients in Group A and 20%(n=5:UC=2,CD=3) of patients in Group B were at moderate risk of malnutrition (MUST=1) and 19% (n=19:UC=15,CD=4) of patients in Group A and 48%(n=12:UC=10,CD=2) of patients in Group B were at high risk of malnutrition (MUST≥2). Overall, 43% of patients in Group A and 68% of patients in Group B were at some form of risk of malnutrition according to MUST score. In a study by Haskey et al, MUST considered that 15.5% (n=17) of the patients were at some nutritional risk with 4.5% (n=5) at high risk and 10.9% (n=12) at medium risk[62]. In

a study by Rahman et al, 36% of UC patients were at malnutrition risk and 48% of CD patients were at malnutrition risk according to MUST scores and a high percentage of patients were at moderate or high malnutrition risk using the MUST screening tool (45.5%)[61]. When MUST score was used, patients deemed to be at risk using MUST had significantly lower BMI, MAC, Triceps Skin Fold Thickness and albumin levels. This was similar to a study by Rahman et el where significant associations were observed between increased nutritional risk using MUST and decreased albumin (OR 1.96, $p<0.001$)[61].

According to SaskIBD score at baseline, 34% (n=34:UC=29,CD=5) of patients in Group A and 68% (n=17:UC=13,CD=4) of patients in Group B were at moderate risk of malnutrition (SaskIBD=3-4) and 3% (n=3:UC=3,CD=0) of patients in Group A and 12% (n=3:UC=2,CD=1) of patients in Group B were at high risk of malnutrition (SaskIBD≥5). Overall, 37% of patients in Group A and 80% of patients in Group B were at some form of risk of malnutrition according to SaskIBD score. In a study by Haskey et al on IBD patients, the SaskIBD tool classified 19.1% (n=21) of the patients at some nutritional risk: 9 (8.2%) at high and 12 (10.9%) at medium risk[62].

In Group A during follow up, 3 patients were lost to follow up at the start of the study and 9 were lost to further follow up after 6 months. Out of the remaining 88 patients, 72 (81.82%) remained in remission, 16 (18.18%) had an episode of relapse, 4 (4.54%) among them had to be hospitalised and treated with intravenous steroids and antibiotics. No patient in Group A had to undergo surgery or had any mortality on follow up. In the study by Jansen et al, 20.8% of CD patients had at least one flare-up within the study period of six months, 22.6% patients suffered from complications (stenosis, fistula, abscess), 20.8% were admitted to the hospital and 11.3% had to undergo surgery[59]. Higher complications in that study could be due to the fact that patients in that study were on more drugs for CD at baseline: Prednisolone (<20 mg/d)18.2%, oral budesonide 5.5%, azathioprine 52.7%, mesalazine 7.3%, methotrexate 3.6%, infliximab 27.3% and adalimumab

10.9%.This could reflect more severe baseline disease. Also, the mean CRP levels in that that study were higher compared to our study reflecting some degree of subclinical inflammation resulting in higher relapse rates.

In Group B during follow up, 3 patients were lost to follow up at the start of the study and 3 were lost to further follow up after 6 months. Out of the remaining 19 patients, disease went into remission in 17 patients, disease remained active in 2 patients at 1 year even after dose escalation. Among 17 patients that went in remission, 3 had an episode of relapse during follow up period of 1 year requiring a course of antibiotics and dose escalation.

In Group A, when comparing nutritional parameters between patients who remained in remission versus those who relapsed on follow up, SaskIBD, and albumin levels had significant associations with p value <0.05. Baseline handgrip strength and BMI had no influence on clinical course in our study. This result was similar to the study by Jansen et al in CD patients where hand grip strength, BMI and body composition had no influence on the clinical course[59].

In Group A, when comparing the percentage of patients who relapsed in low risk MIRT group with the percentage of patients who relapsed in at risk MIRT group, the difference in percentage was found to be non-significant. In a study by Jensen et al, MIRT significantly predicted outcome in numerous nutritional and clinical parameters (SGA, CD-related flares, hospitalisations and surgeries) in patients with CD[59]. Such similar results could not be reproduced in our study probably because of small number of CD patients in our study in remission group (n=18) as compared to study by Jansen et al (n=55)[61].

In Group A, when comparing the percentage of patients who relapsed in low risk MUST group (Score 0) with the percentage of patients who relapsed in moderate to high risk MUST group (Score ≥1), although the percentage of patients who relapsed were high in the latter (12.5% vs 24.4%), the difference in percentage was not found to be statistically

significant. But when similar stats were applied to patients with low to intermediate risk MUST group (Score 0-1) versus high risk group (Score ≥2), the difference in percentage of patients who went in disease relapse became statistically significant. This indicates that MUST score had better specificity for detecting nutrition risk at higher values (Score ≥2).

In Group A, when comparing the percentage of patients who relapsed in low risk SaskIBD group with the percentage of patients who relapsed in moderate to high risk SaskIBD group, the difference in percentage was found to be statistically significant with P value <0.05.Similar results were shown in study by Haskey et al, which concluded that SaskIBD score had significant agreement with the RD/GI assessment (k 0.83, p<0.001), and had better sensitivity (82.6% vs 26.1%), specificity (97.7% vs 87.4%), positive predictive value (90.5% vs 35.3%), and negative predictive value (95.5% vs 81.7%) than the MUST for detecting patients at risk of malnutrition[62].

In Group B, when comparing nutritional parameters between patients who remained in remission versus those who relapsed on follow up, only albumin levels had significant associations with p value <0.05. Although MIRT, MUST & SaskIBD had higher mean values in patients who had persistently active disease/relapse, but the difference failed to reach significant values. This may be due to the small sample size in Group B during follow up (n=19).

When assessing the impact of baseline Nutritional Screening Tools on outcomes during follow up in Group B, on comparing the percentage of patients who relapsed in low risk groups with the percentage of patients who relapsed in at risk groups, the difference was found to be non-significant. This again may be due to the small sample size in Group B during follow up.

Our study had a few limitations. There was no control group to compare the nutrition parameters with IBD patients. The sample size of

patients with CD was small (Group A n=18; Group B n=6). The sample size of patients with active disease at enrolment was small (n=25).

Our study if the first of its kind, assessing the nutritional status and its effect on clincal outcomes in Indian patients with IBD. However, there were a few limitations like the lack of a control group to compare nutritional status of IBD patients with normal population and a small number of patients in group B (active disease). Further studies, involving more patients from other centres in the country should be planned and various NSTs/NATs should be validated in Indian population. Clinical care pathways including screening, assessment and nutritional intervention during IBD clinic visits should be developed to ensure better clinical outcomes in Indian patients with IBD.

SUMMARY AND CONCLUSION

This study was conducted in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India. One hundred and twenty five patients were enrolled during the study period: 100 patients were in remission (Group A) and 25 patients were newly diagnosed active cases at the time of enrolment (Group B).The nutritional status among IBD patients in our study was assessed by using Nutrition Screening Tools: MIRT, MUST and SASK IBD, and Nutrition Assessment Tools: anthropometric data, handgrip strength, haemoglobin and albumin levels. Patients were followed-up for their clinical course of disease resulting in flare-ups, hospitalisations, surgery and death/mortality. Following were the salient features of this study.

- Mean age of patients in our study was 40.27±13.23 years (Group A 40.46±13.13, Group B 39.52±13.90, p=0.736).
- UC (n=101, 80.8%) was more common than CD (n=24, 19.2%), with a UC:CD ratio of 4.2:1 (Group A UC:CD=4.5:1, Group B UC:CD=3.1:1).
- Mean BMI of patients in the study was 23.82±4.88 kg/m^2 (Group A 24.22±4.74, Group B 22.24±5.20:p=0.018).
- Twelve percent of patients in our study were underweight (Group A 11%, Group B 16%), 33.6% patients were overweight (Group A 39%, Group B 12%) and 16.8% patients were obese (Group A 17%, Group B 16%).
- Mean MAC of patients in the study was 26.26±3.30 cm (Group A 26.57±3.27, Group B 24.98±3.14: p=0.032).
- Mean triceps skin fold thickness of patients in the study was 13.57±7.60 mm (Group A 14.10±7.47, Group B 11.44±7.90: p=0.071).
- Mean hand grip strength of patients in the study was 28.58±10.20 kg (Group A 29.23±10.11, Group B 25.96±10.36: p=0.189).

- Mean CRP of patients in the study was 5.97±8.67 mg/L (Group A 3.98±4.96, Group B 13.95±14.29: p=0.001).
- Mean albumin levels of patients in our study were3.37±0.42 g/dL (Group A 3.40±0.42, Group B 3.28±0.40: p=0.178).
- Using the NSTs, higher percentage of patients in Group B were found to be at a risk of malnutrition, as compared to Group A [MIRT≥3 (Group A 4%, Group B 32%), MUST≥1 (Group A 43%, Group B 68%), SaskIBD≥3 (Group A 37%, Group B 80%)].
- Nutritional Assessment using various NATs found a significantly lower BMI, MAC and Triceps Skinfold Thickness in patients with active disease in UC patients, when compared to those who were in remission at the time of recruitment. However, none of the NATs revealed a significant difference in the nutritional status of the CD patients.
- At 1 year of follow up, 12 and 6 patients were lost to follow up in groups A and B respectively.
- Of the 88 patients analysed in Group A, at 1 year follow up, 72 (81.82%) were in remission and 16 (18.18%) relapsed, 4 (4.54%) among them had to be hospitalised and treated with intravenous steroids and antibiotics. No patient in Group A had to undergo surgery or had any mortality on follow up.
- Out of the 19 patients in group B, disease went into remission in 17 patients (89.47%), disease remained active in 2 patients (10.53%) at 1 year even after dose escalation. Among 17 patients that went in remission, 3 had an episode of relapse during follow up period of 1 year requiring a course of antibiotics and dose escalation.
- On baseline nutritional screening with NSTs, SaskIBD score of ≥3 and MUST score of ≥ 2 could predict poor clinical outcomes at the end of 1 year of follow up in group A, while none of the NSTs showed a significant correlation with clinical outcomes at 1 year follow up in Group B.

  The disease course in patients with IBD is affected by both malnutrition and active inflammation. Among patients with IBD,

those with active disease and higher risk of malnutrition at baseline screening using NSTs like MUST and SaskIBD have poorer clinical outcomes at follow up. A high prevalence of malnutrition was seen on detailed nutritional assessment, with significantly lower BMI, MAC and serum albumin levels and higher CRP in patients with active disease. Lower serum albumin levels showed correlation with poor clinical outcomes. As recommended by various guidelines, nutritional screening should be done for all patients with IBD at time of diagnosis, as well on annual follow up. Detailed nutritional assessment should be done for patients at risk and adequate nutritional interventions done to improve nutritional status and thereby achieve better clinical outcomes in these patients.

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Date 8/9/21

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Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of Dr Sumeet Singh, a student of your college for DM Medical Gastroenterology along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Nutritional status in inflammatory bowel disease and its impact on clinical course

Supervisor
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Co-Supervisor
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The student has to submit the three copies of thesis (along with PDF format), to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note:

8. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED
IN PARTIAL FULFILMENT OF THE REQUIREMENTS
FOR THE DEGREE OF

DOCTORATE OF MEDICINE

IN

GASTROENTEROLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

MARCH, 2020

DR. SUMEET SINGH

DEPARTMENT OF GASTROENTEROLOGY

DAYANAND MEDICAL COLLEGE, LUDHIANA, PUNJAB, INDIA

ABSTRACT OF PLAN OF THESIS

Title	**NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE**
For the degree of	D.M. (Gastroenterology)
Name of the candidate	**Dr. Sumeet Singh**
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Introduction: Crohn's disease (CD) and ulcerative colitis (UC) are chronic, relapsing, inflammatory disorders of the digestive tract that characteristically develop in adolescence and early adulthood. Malnutrition is one of the most important factors associated with a poor clinical outcome in patients with IBD. This study intends to assess the nutritional status of patients of IBD using the NSTs and NATs and study the correlation of nutritional status with disease course and complications.

AIM: To study the nutritional status in patients with Inflammatory Bowel Disease and study the correlation of nutritional status with disease course and complications.

MATERIAL AND METHOD: Prospective study which will be conducted on patients attending the outpatient department or admitted in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India.

CLINICAL SIGNIFICANCE: To see if nutritional status has an effect on disease course.

Keywords: CD: Crohn Disease, UC: Ulcerative Colitis, IBD: Inflammatory Bowel Disease.

Candidate's Sign Co-supervisor's Sign Supervisor's Sign Principal's Sign

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE"** exist in the Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate himself/herself under our supervision and guidance.

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APPROVAL PROFORMA
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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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2	**NAME OF THE INSTITUTE**	DAYANAND MEDICAL COLLEGE AND HOSPITAL, TAGORE NAGAR CIVIL LINES, LUDHIANA
3	**COURSE OF STUDY AND SUBJECT**	DOCTORATE IN MEDICINE (D.M.) GASTROENTEROLOGY
4	**DATE OF ADMISSION OF COURSE**	3rd September, 2019
5	**TITLE OF THE TOPIC**	NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Crohn's disease (CD) and ulcerative colitis (UC) are chronic, relapsing, inflammatory disorders of the digestive tract that characteristically develop in adolescence and early adulthood. The reported prevalence of malnutrition in inflammatory bowel disease (IBD) patients ranges between 20% and 85%.[1] Several studies have reported a prevalence of weight loss in 70%–80% of hospitalized IBD patients and in 20%–40% of outpatients with CD.[2] The prevalence of protein–energy and specific nutrient malnutrition is higher in CD compared to UC because CD can affect any part of the gastrointestinal tract and, mainly, the small bowel.

Malnutrition is a common condition among IBD patients and can be recognized by protein–energy malnutrition, an altered body composition, and micronutrient deficiencies and their prevention is essential to avoid complications.

Malnutrition is one of the most important factors associated with a poor clinical outcome in patients with IBD. The severity of malnutrition in IBD patients is dependent on the activity, duration and extent of the disease and on the magnitude of the inflammatory systemic response.

The reported rates of malnutrition in outpatient IBD clinics vary on how malnutrition is defined and measured. The current literature focuses on protein-energy malnutrition and specific micronutrient deficiencies, such as Vitamin D deficiency. When utilizing validated assessment methods of assessing protein-energy malnutrition such as the Subjective Global Assessment (SGA), rates of malnutrition have been reported to be as high as 24% in patients with IBD in clinical remission and 64% of patients with active IBD.[3] Many reported prevalence rates of malnutrition are based on specific anthropometric and laboratory measures, such as body mass index (BMI), skinfold thickness, mid-arm circumference and serum protein levels.[4]

However, these measures do not take into account decreased oral 'intake and disease-related effects on the nutritional state.

Furthermore, some of these measures are not practical in a setting of a busy outpatient clinic and relying exclusively on serum protein levels, such as serum albumin, can be misleading.

Challenges in screening nutritional status

The earlier studies focused on the Subjective Global Assessment (SGA). The SGA is more of an assessment tool rather than a screening tool, and requires expertise in nutritional assessment, limiting its ease of use. In the setting of an academic center with a focus on drug trials, and multiple assessments performed by attending physicians, medical learners, nurses, research assistants, and other allied health professionals, the pressure to perform these tasks in a short time period can limit nutritional screening.[5] Additionally, the absence of objective values makes teaching the methodology of SGA difficult and resource intensive.

Nutritional risk screening (NRS) is a process to predict those at risk of malnutrition so that they can be referred to a registered dietitian (RD) for detailed nutritional assessment and intervention. Nutrition screening tools (NSTs) (i.e., the malnutrition universal screening tool (MUST), malnutrition inflammation research tool (MIRT), nutrition risk screening (NRS 2002), SASK-IBD are rapid evaluations that can be completed by any member of the medical team whereas nutrition assessment tools (NATs) (i.e., CT-MSI, hand grip strength, BMI, MAC, Biochemistry parameters) are usually more detailed and require greater specialized resources. As recent studies have demonstrated a close relationship between malnutrition and sarcopenia, many expert groups now incorporate measures of lean muscle mass within the definition of malnutrition[6].

To date, there are no published recommendations that exist for use of a specific NST or NAT in IBD.[7] Although there have been isolated reviews of sarcopenia in IBD[8], a practical approach to nutrition screening and treatment is more extensive than sarcopenia assessment alone.

There is a limited amount of data available to compare NSTs to NATs. Four NSTs (the MUST, NRS-2002, MIRT and SaskIBD-NRT) shows

promise. The MUST includes BMI, unplanned weight loss in the past 3-6 months and an acute disease effect score. The MIRT measures similar criteria, including BMI, unintentional weight loss and CRP. Therefore, these two tools vary only in the method that acute disease is assessed. The NRS-2002 differs from the two previous tools, as it captures reduced dietary intake in addition to BMI, weight loss and ICU admission status, and has been validated in the inpatient population. The SaskIBD-NRT is a novel tool based on patient history evaluating gastrointestinal symptoms and food restriction behaviors commonly seen in the IBD population in addition to the more common screening questions of weight loss and poor oral intake.[9] The SaskIBD-NRT is reliant on nutrition specific data points to assess risk.

This study intends to assess the nutritional status of patients of IBD using the NSTs and NATs and study the correlation of nutritional status with disease course and complications.

6.2 REVIEW OF LITERATURE

The mechanisms underlying malnutrition in inflammatory bowel disease include reduced oral food intake, malabsorption of nutrients, enteric nutrient loss, increased energy requirements due to systemic inflammation and, occasionally, iatrogenic factors (drug- and surgery-related). The assessment of the nutritional status and the need of supportive nutritional therapy play a pivotal role in the clinical care of inflammatory bowel disease patients.

Malnutrition is one of the most important factors associated with a poor clinical outcome in patients with IBD.[10] Among IBD patients, significant differences in the nutritional status between CD and UC patients have been described, since the involvement of the small intestine is accompanied by a higher incidence of protein–energy malnutrition and micronutrient and/or vitamin deficiencies. Moreover, patients with CD generally develop malnutrition over a long period of time, whereas patients with UC tend to present a precipitous nutritional deficiency during a severe acute flare of the disease or in case of hospitalization.

Sarcopenia is a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strength with risk of poor quality of life and physical disability. Principal mechanisms involved in genesis of sarcopenia are malnutrition, immobility, low protein synthesis, and increased proteolysis.[11] Diagnosis of sarcopenia comprehends the demonstrations of both muscle mass and muscle strength.

The gold standard to asses muscle mass is DXA, computed tomography (CT), or magnetic resonance imaging (MRI). Muscle strength is assessed with a grip strength test, which is of low cost and is an easy-to-handle technique, using a standard dynamometer. Recent evidences suggest that prevalence of sarcopenia is up to 12% in CD patients evaluated with the appendicular skeletal muscle index (ASMI) asserted with whole-body DXA. Hand grip strength test is a positive predictor of low ASMI compared to BMI.

A study by Ryan E reported that up to 60% IBD patients have decreased muscle mass when compared with healthy subjects.[8] Adams et al. showed that a significant proportion of IBD patients who had sarcopenia (41.5%) presented a normal body mass index (BMI) and, therefore, would not be identified as undernourished by traditional measures and 20% of sarcopenic patients in this cohort were overweight or obese.[12] Sarcopenia has been associated with an increased need for surgery and poor surgical outcomes in IBD, as well as with osteopenia.[13] This highlights the need for malnutrition and/or sarcopenia screening in all IBD patients.

The most common micronutrient deficiencies in IBD patients concern iron, calcium, selenium, zinc, magnesium, water-soluble vitamins, in particular, B12 and folic acid, and fat-soluble vitamins, such as A, D, and K.

Anemia is the most frequent systemic complication and extra-intestinal manifestation of IBD.[14] Iron deficiency is the main cause of anemia in the adult IBD population, with a prevalence between 36% and 90%. The main factors determining iron deficiency in IBD are: inadequate iron intake in the diet, active inflammation leading to a continuous blood loss from the ulcerated surface of the bowel, impaired iron utilization due to the systemic inflammatory status, and impaired iron uptake through the duodeno–jejunal mucosa. Unlike ferritin, chronic inflammation has no effect on soluble transferrin receptor (sTfR) levels, and the concentration of sTfR in the serum may be considered an indicator of the supply of iron available for erythropoiesis.[15]

Overview of Nutritional Assessment

The nutritional assessment should include a dietetic evaluation with the assessment of daily caloric intake and energy expenditure, radiological assessment, and measurement of functional capacity. According to the World Health Organization standardized criteria, patients are considered well nourished when their BMI is between 18.5 and 24.5 kg/m2, underweight or malnourished when their BMI is 18.5 kg/m2, and overweight when their BMI is 25 kg/m2.[3]

Several methods can be employed to reach a full characterization of the body composition. Computerized tomography and magnetic resonance provide a radiological measurement of muscle mass: skeletal muscle index (SMI) at the level of the third lumbar vertebral body, cross-sectional area of the psoas muscles (the total psoas area index), or psoas muscle density using mean Hounsfield unit average calculations (HUAC) are indirect indicators of the sarcopenic status.[16] Muscle function can be clinically investigated to aid in the diagnosis of sarcopenia by measuring either hand grip strength, using a standard dynamometer, or gait speed.[17]

MUST is designed to identify patients at risk of malnutrition, which could benefit from nutritional intervention; it has good success on hospitals evaluations because of its simplicity, reliability, and validity. The nutritional risk is assessed with the identification of weight and height to calculate BMI, assessment of unintentional weight loss in the last 3–6 months, and the presence of any acute medical condition, in which there was an insufficient food intake calculated for a period equal to or greater than 5 days.The total score ranges from 0 to 2, indicating the presence of a mild, moderate, or severe risk of malnutrition (low risk = 0, moderate risk = 1, and severe risk = 2).[16]

NRS is commonly used for hospitalized patients.[9] It starts by same parameters of MUST, adding the degree of severity of diseases and age. NRS 2002 is divided into two parts: an initial screening consisting in 4 questions (BMI below 20.5, weight loss in the last three months, reduced food intake in the last week, and the presence of severe acute disease) and a second part consisting in the evaluation of degree of malnutrition associated with the severity of the disease and age. The second part of the questionnaire is completed if at least one of the four initial questions is positive; a score higher than 3 identifies patients at higher nutritional risk. These last patients require stronger therapeutic intervention.

The MIRT and SaskIBD-NRT have shown significant associations with more comprehensive nutritional assessment methods. The MIRT has an association with an abnormal SGA. SaskIBD-NRT show strong

agreement to subsequent comprehensive assessment by RD/GI. This association has not been consistent with one study noting poor inter-rater agreement between MUST and a comprehensive RD/GI assessment.[19] Recognizing sarcopenia as an integral, objective component of malnutrition, both the MUST and NRS-2002 demonstrated a significant association with sarcopenia as measured by the SMI.

In a study conducted by Rahman A et al using MUST score in patients with IBD, it was concluded that a high MUST score was strongly associated elevated Harvey Bradshaw Index scores (p=0.005) for patients with Crohn's disease, but not with the Partial Mayo Index scores (p=0.597) for patients with ulcerative colitis. Significant associations were noted in the odds of elevated nutritional risk and decreased albumin (OR 1.96, p<0.001), decreased Vitamin D (OR 1.51 p=0.032), and decreased creatinine (OR 1.47, p=0.050) which concluded that MUST predicts disease activity in patients with Crohn's disease but there is a floor effect.[20]

In a study by Jensen Irene on fifty-five patients with CD in remission (Crohn's disease activity index (CDAI)<200) at 0 and 6 months assessing disease activity (CDAI, Harvey–Bradshaw index), inflammation (C-reactive protein (CRP), faecal calprotectin (FC)), malnutrition (BMI, subjective global assessment (SGA), serum albumin, handgrip strength), body composition (bioelectrical impedance analysis) and 'Malnutrition Inflammation Risk Tool' (MIRT; containing BMI, unintentional weight loss over 3 months and CRP). All parameters were evaluated regarding their ability to predict disease outcome prospectively at 6 months. At baseline, more than one-third of patients showed elevated inflammatory markers despite clinical remission (36·4 % CRP≥5mg/l, 41·5% FC≥100µg/g). Prevalence of malnutrition at baseline according to BMI, SGA and serum albumin was 2–16 %. At 6 months, MIRT significantly predicted outcome in numerous nutritional and clinical parameters (SGA, CD-relatedflares, hospitalisations and surgeries). In contrast, SGA, handgrip strength, BMI, albumin and body composition had no influence on the clinical course. The newly

developed MIRT was found to reliably predict clinical outcome in CD patients.[21]

In a study by Natasha Haskey to detect nutrition risk in patients with inflammatory bowel disease, the Saskatchewan IBD–Nutrition Risk (SaskIBD-NR Tool) was developed and administered alongside the Malnutrition Universal Screening Tool (MUST). It was shown that The SaskIBD-NR tool had significant agreement with the RD/GI assessment (k 0.83, $p<0.001$), while MUST showed a lack of agreement (k 0.15, $p=0.12$). The SaskIBD-NR had better sensitivity (82.6% vs 26.1%), specificity (97.7% vs 87.4%), positive predictive value (90.5% vs 35.3%), and negative predictive value (95.5% vs 81.7%) than the MUST. It cocluded that The SaskIBD-NR, which assesses GI symptoms, food restriction, and weight loss, adequately detects nutrition risk in IBD patients.[9]

Nutritional aspects in IBD are particularly relevant as they potentially influence disease activity and, therefore, its morbidity. Results from the currently available literature show that a poor nutritional status, as well as selective malnutrition or sarcopenia, is associated with poor clinical outcomes, response to therapy, and, therefore, quality of life. Several factors contribute to malnutrition in IBD patient. The nutritional assessment should include a dietetic evaluation with the assessment of daily caloric intake and energy expenditure, radiological assessment, and measurement of the functional capacity. This study aims to see the nutritional status of patients with IBD using NSTs and NATs and find out if they have a positive relationship with disease course and complications.

6.3 AIMS AND OBJECTIVES OF THE STUDY

1. To study the nutritional status in patients with Inflammatory Bowel Disease.
2. To study the correlation of nutritional status with disease course and complications.

7. MATERIALS AND METHODS

STUDY DESIGN

This study will be conducted on the patients attending the outpatient department or admitted in Department of Gastroenterology, Dayanand Medical College and Hospital, Ludhiana, India.

Patients already diagnosed with IBD and newly diagnosed patients attending the outpatient or admitted indoors in Department of Gastroenterology, DMC & H will be enrolled for the study.

Patients suffering from IBD will be enrolled after obtaining informed consent. Patients will be divided into two groups :

1. Already diagnosed and in clinical remission: 100 patients
2. Newly diagnosed patients: 25

New patients will be diagnosed with colonoscopy/sigmoidoscopy, histopathological biopsy and CT/CT enterography/MR enterography (where required).

Already diagnosed patients will be classified in remission by CDAI (Crohns Disease Activity Index) for Crohns Disease and Total Mayo score for Ulcerative Colitis at baseline.

For remission CDAI should be less than 150 for CD and total mayo score should be equal to or less than 2 for UC.

Nutritional status will be studied in patients by Nutrition Screening Tools (NST) and Nutrition Assessment Tools (NAT). NST will include MIRT (Malnutrition Inflammation Risk Tool), MUST (Malnutrition Universal Screening Tool),NRS 2002 (Nutrition Risk Screening 2002) and SASK IBD whereas NAT will include anthropometry parameters like height, weight, BMI, mid arm circumference: biochemical markers like serum albumin, heamoglobin, transferrin saturation, calcium, magnesium, Vitamin D, folate, Vit B12 levels: sarcopenic assessment using handgrip strength.

MIRT & MUST will be applied to outpatients whereas NRS 2002 will be applied to inpatients.

Baseline values will be obtained for each patient and patients will be followed up every three months for 1 year to monitor disease

progression, complications, and relapse.

The subjects will be continued on their standard of care pharmacological maintenance regimen with 5-ASA compounds/ immunomodulators.

7.1 SOURCES OF DATA

Consecutive patients suffering from IBD who are in remission and newly diagnosed IBD patients attending the outpatient or admitted indoors in Department of Gastroenterology, DMC & H will be enrolled for the study.

7.2 METHODS OF COLLECTION OF DATA

Confirmed cases of IBD will be enrolled and their nutritional status assessed using MIRT, MUST (for outpatients) NRS 2002 (for inpatients) and SASK IBD. Patients will be followed-up every 3 months till a total period of one year for disease characteristics at baseline, course, complications and mortality. Subjects will be continued on their standard pharmacotherapy.

INCLUSION CRITERIA

1 Age >18 years
2 Confirmed IBD patients who are in remission
3 Newly diagnosed IBD patients
4 Able to give informed consent and/or assent as appropriate

EXCLUSION CRITERIA

1 Patients in relapse
2 Patients unwilling or unable to give consent or participate in all study requirements

SCALES AND SCORES

The Mayo Score for ulcerative colitis disease activity provides an assessment of disease severity and can be used to monitor patients during therapy. The score can range from 0-12 with higher scores indicating worse severity. A score of equal to,or less than 2 indicates remission.

The Clinical Mayo Score or Partial Mayo Score (PMS), uses the three non-invasive components of the full Mayo Score (stool frequency, rectal bleeding and Physician's global assessment). This excludes the score for the endoscopic findings, therefore the maximum score is reduced from 12 to 9 points.

The Crohn's Disease Activity Index (CDAI) combines weighted scores of clinical and laboratory variables to estimate disease severity. CDAI scores of less than 150 indicate a clinical remission and scores over 450 indicate severely active disease. Main components of the CDAI are patient-reported symptoms such as diarrhoea, abdominal pain and overall well-being referring to the last week before assessment. Furthermore, it includes, the presence of extra-intestinal manifestations, haematocrit and ratio of actual body weight: standard body weight.

MIRT is composed of the objective parameters BMI, unintended weight loss and CRP in order to combine both nutrition- and inflammation-related measures. It has a total score of 8 points. Higher score values indicate more risk of malnutrition.

MUST is a five-step screening tool to identify adults, who are malnourished, at risk of malnutrition (undernutrition), or obese. It also includes management guidelines which can be used to develop a care plan. It is for use in hospitals, community and other care settings and can be used by all care workers.

Step 1: Measure height and weight to get a BMI score.

Step 2: Note percentage unplanned weight loss and score using tables provided.

Step 3: Establish acute disease effect and score.

Step 4: Add scores from steps 1, 2 and 3 together to obtain overall risk of malnutrition. Total score of 0 signifies low risk, score of 1 signifies medium risk and score of 2 or more signifies high risk of malnutrition.

Step 5: Use management guidelines and/or local policy to develop care plan.

SaskIBD-NR tool considers symptoms (nausea, vomiting, and diarrhea), nutrient intake (food intake and food avoidance), and unintentional weight loss, all of which are all well-defined risk factors for malnutrition in the IBD outpatient population. Questions pertaining to symptoms gauge IBD disease activity (active or remission). Questions pertaining to nutrient intake screen for potential micronutrient deficiency. Questions relating to weight loss screen for potential protein-energy malnutrition. It has a total score of 9 points. A score of 0-2 signifies low risk, 3-4 signifies medium risk and 5 or more score signifies high risk of malnutrition.

The NRS 2002 consists of an initial and a final screening. The final screening involves completing a questionnaire covering nutritional score (loss of body weight, BMI, and food intake), severity of disease score, and age adjustment for patients aged >70 years. Patients are classified based on the total of each score as being with or without nutritional risk. A score of 3 or more indicates patient is at risk of malnutrition.

DURATION OF STUDY

Patients will be enrolled from April 2020 to September 2020 and will be followed up every three months for a period of 1 year till August 2021.

OUTCOME

Primary Outcome

To study the nutritional status in patients with Inflammatory Bowel Disease.

Secondary Outcome

To study the correlation of nutritional status with disease course and complications.

STATISTICAL ANALYSIS

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. For comparing categorical data, Chi square ($\chi 2$) test will be performed and exact test was used when the

expected frequency is less than 5. A probability value (p value)less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

- Yes, the study requires investigations

Haemoglobin

CRP Quantitative/ hs CRP

Albumin

Ferritin

Iron

TIBC

TS

Calcium

Magnesium

Vit. D

L3 skeletal muscle mass index (If Available)

Vit. B12

Folate

Fecal Calprotectin

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached herewith.

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PROFORMA

SR no.	Patient ID	Date
CR no.	Admn. no	UC/CD
Name	Age	Sex
Address		
Contact number		
Year of diagnosis		
Duration of disease		
Family history of IBD: Yes/No		(If Yes, specify)
Appendicectomy:	Yes/No	

Disease Characteristics at Enrolment

Ulcerative Colitis		**Crohn's Disease**	
Colonoscopic Extent		Classification	A L B P
		CDAI	
Partial Mayo Score		CTE/MRE/ DBE/ Colonoscopy/UGIE (if Required)	
Total Mayo Clinic Score		Capsule Endoscopy (If Required)	
Histopathology	**Supportive/ Consistent**	Histopathology	**Supportive/ Consistent**

Personal and Past History

Previous Medications	
ATT	
Alternative Medicine	
Others (if any)	
Past History	
Tuberculosis	
Chicken pox/shingles	

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Jaundice	
Surgery	
Comorbidities	
Liver Disease/DM/HTN/Others	
Family History	
IBD/Liver Disease/Tuberculosis/Others	

Treatment (Kindly tick mark and mention route/dose)					
	Baseline	**3 months**	**6 months**	**9 months**	**1 year**
5-ASA					
Steroids					
AZA					
6-MP					
Antibiotics					
Probiotics					
CYS					
MTX					
IFX					
ADA					
VDZ					
TAC					
Curcumin					
FMT					
Others					

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	Baseline	3 months	6 months	9 months	1 year
Quiescent					
Active					

Nutritional Screening and Assessment

Dietary History : Vegetarian (Semi, Pesco, Lacto-ovo)/Non vegetarian/Vegan

Clinical History

	Baseline*	3 months	6 months	9 months	1 year*
Fatigue, Dyspnea on exertion Weakness, Tiredness, Bodyaches, Muscle Cramps, Restless Leg Syndrome					
Peripheral Neuropathy :Numbness/Tingling Sensation/Burning/Reduced sensations/Imbalance					
Infertility					
Bony pains, Fractures with minimal trauma					
Disturbed smell and taste					
Poor wound healing					
Night blindness, Xerophthalmia					
Oral ulcers					
Bleeding tendencies, beeding gums, petechiae, ecchymosis					
Weight loss, anorexia, nausea, vomiting					
Delayed growth parameters (especially in pediatric IBD; milestones/Weight for age/Height for age/Weight for height)					

Signature of Candidate **Signature of Supervisor**

Anthropometry

	Baseline*	3 months	6 months	9 months	1 year*
Height (m)					
Weight (kg)					
BMI (kg/sq.m)					
Handgrip Strength					
Mid Arm Circumference					
CT/MRI Index (if available)					

Investigations

	Baseline*	3 months	6 months	9 months	1 year*
Haemoglobin					
CRP Quantitative/ hs CRP					
Albumin					
Ferritin					
Iron					
TIBC					
TS					
Calcium					
Magnesium					
Vit. D					
Fecal Calprotectin					
L3 skeletal muscle mass index					
Vit. B12					
Folate					
Others (if any)					

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Nutritional Screening Tools

	Baseline*	3 months	6 months	9 months	1 year*
MIRT					
MUST					
NRS 2002 (if hospitalized)					
SASK IBD					

24 hours food recall/3 day food diary

Intake	Baseline*	3 months	6 months	9 months	1 year*
Breakfast					
Mid day					
Lunch					
Evening					
Dinner					
Post dinner					
Energy intake (kCal)					
Protein intake (g)					
Fat intake (g)					
Adequacy of diet					
Comments (if any)					

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

I.....D/o, W/o, S/o **"NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE".** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____ निवासी _____ इस शोधकार्य **"NUTRITIONAL STATUS IN INFLAMMATORY BOWEL DISEASE AND ITS IMPACT ON CLINICAL COURSE"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

विद्यार्थी के हस्ताक्षर

Sr. No	MRD	Age	Sex	UC	CD	Disease Duration	Disease Extent UC	Montreal Class CD	CDAI	Total Mayo Score	Partial Mayo Score	Disease Activity At Baseline	Height	Weight	BMI	BMI	MAC	Hand Grip Strength	Triceps Skin Fold Thickness	MIRT	MUST	SASK IBD	Skeletal Muscle Area	SMI	Hb	CRP
1	1008011	52	M	-	YES	7	-	3,3,2	143	-	-	Remission	1.67	61	22	2	28.5	40	7	2	2	3	85.43	30.63	6.1	12.45
2	971920	18	M	YES	-	2	E2	-	-	2	1	Remission	1.72	63	21	2	25	35	6	1	0	1	-	0.00	11	7.65
3	477324	34	M	YES	-	3	E2	-	-	2	1	Remission	1.8	61	19	2	26	40	3	1	1	2	-	0.00	10.6	2.67
4	295265	71	F	YES	-	14	E2	-	-	2	2	Remission	1.58	54	22	2	22	14	7	1	0	0	-	0.00	8.6	6.43
5	419757	58	M	YES	-	4	E2	-	-	2	1	Remission	1.68	57	20	2	25	22	8	2	1	3	-	0.00	12.8	6.23
6	752767	18	F	YES	-	3	E2	-	-	2	2	Remission	1.61	51	20	2	23	20	11	1	1	1	-	0.00	10.1	1.34
7	910286	24	M	-	Yes	1	-	2,3,3	138	-	-	Remission	1.84	57	17	1	24	30	2	2	2	4	-	0.00	12.8	0.17
8	44987	45	F	YES	-	16	E2	-	-	2	1	Remission	1.57	66	27	4	26	29	19	0	0	1	-	0.00	12	0.89
9	678866	30	F	-	YES	3	-	2,1,1	142	-	-	Remission	1.64	65	24	3	28.5	36	31	0	0	0	-	0.00	9.1	1.23
10	1022598	24	M	YES	-	2	E2	-	-	2	1	Remission	1.8	66	20	2	24.5	42	6	1	1	1	-	0.00	13.7	1.53
11	55667	37	F	YES	-	6	E1	-	-	2	2	Remission	1.63	66	24	3	30	28	32	0	0	1	-	0.00	9	1.13
12	1026008	41	M	YES	-	2	E2	-	-	2	2	Remission	1.68	78	26	4	30	41	12	0	0	0	-	0.00	12	0.65
13	83920	46	F	YES	-	19	E2	-	-	2	1	Remission	1.61	58	22	2	24	20	17	0	0	1	-	0.00	12.2	0.34
14	653618	24	M	-	YES	3	-	2,1,1	59	-	-	Remission	1.68	67	23	3	27	32	10	0	0	1	-	0.00	12.5	0.74
15	823162	35	F	YES	-	2	E1	-	-	2	1	Remission	1.52	61	25	4	27	20	20	0	0	0	-	0.00	10.1	0.31
16	468117	31	M	-	YES	3	-	2,3,1	68	-	-	Remission	1.76	98	38	5	33.3	51	22	0	0	1	136	43.90	13	3.05
17	674382	53	F	YES	-	3	E2	-	-	2	1	Remission	1.54	61	26	4	28	20	9	0	0	2	-	0.00	11	1.13
18	89456	45	F	-	YES	12	-	2,2,1	113	-	-	Remission	1.51	55	24	3	24	19	10	0	0	2	-	0.00	11.4	2.62
19	365794	35	M	YES	-	11	E2	-	-	2	1	Remission	1.6	48	19	2	23.5	40	7	2	2	2	136.3	53.24	10	2.15
20	1022777	36	F	YES	-	1	E2	-	-	2	1	Remission	1.45	41	20	2	22	20	8	1	1	3	-	0.00	10.7	2.34
21	1002592	28	M	YES	-	1	E3	-	-	2	1	Remission	1.74	63	22	2	26	38	11	0	0	2	-	0.00	10.4	0.45
22	978333	49	M	YES	-	29	E2	-	-	2	1	Remission	1.79	79	25	4	29	34	19	0	0	1	-	0.00	12.4	0.68
23	772061	46	F	YES	-	4	E2	-	-	2	2	Remission	1.53	68	29	4	27.2	25	14	0	0	1	-	0.00	12.8	3.63
24	89295	62	F	YES	-	15	E2	-	-	2	2	Remission	1.57	67	27	4	29	25	20	0	0	1	-	0.00	10.5	2.34
25	971320	35	F	YES	-	1	E1	-	-	2	2	Remission	1.51	54	24	3	24	25	15	0	0	2	-	0.00	7.8	1.39
26	862203	48	F	YES	-	9	E2	-	-	2	1	Remission	1.54	59	25	4	25	12	10	0	0	2	-	0.00	12.5	2.16
27	875884	65	F	Yes	-	5	E2	-	-	2	1	Remission	1.49	56	22	2	28.2	22	10	2	1	4	-	0.00	10	5.67
28	994844	39	F	YES	-	12	E2	-	-	2	1	Remission	1.56	67	28	4	30	32	30	0	0	1	-	0.00	10.7	1.54
29	995283	35	F	YES	-	14	E2	-	-	2	1	Remission	1.61	51	20	2	26	20	8	1	1	2	-	0.00	8.2	1.82
30	939561	29	F	Yes	-	1	E2	-	-	1	1	Remission	1.66	47	17	1	21	27	4	2	2	5	-	0.00	7	1.23
31	70253	65	F	YES	-	23	E2	-	-	2	2	Remission	1.54	64	27	4	28	13	10	0	0	1	79.69	33.60	11	2.62
32	289798	39	M	YES	-	6	E2	-	-	2	2	Remission	1.7	52	18	1	34.5	32	6	2	2	2	92.73	32.09	9.6	2.23
33	509873	32	M	YES	-	13	E2	-	-	2	2	Remission	1.67	77	28	4	28.5	36	12	0	0	2	-	0.00	10.4	1.34
34	1078233	38	M	-	YES	1	-	2,1,2	143	-	-	Remission	1.73	86	29	4	31	50	12	0	0	1	-	0.00	14	1.23
35	26159	39	M	-	YES	2	-	2,3,3	110	-	-	Remission	1.67	76	27	4	31	34	20	1	1	2	-	0.00	10.7	0.56
36	34147	62	F	YES	-	10	E2	-	-	2	2	Remission	1.53	59	25	4	28	23	12	2	1	3	82	35.03	10.8	13.23
37	964449	57	F	YES	-	26	E2	-	-	2	1	Remission	1.58	68	27	4	28	20	12	0	0	1	-	0.00	9.2	0.45
38	850831	50	M	YES	-	9	E1	-	-	2	1	Remission	1.74	115	39	5	35	32	15	2	1	2	112.8	37.26	11.5	13.23
39	675741	23	M	YES	-	2	E2	-	-	2	1	Remission	1.78	68	22	2	24.5	30	17	2	1	3	127.9	40.37	12	7.45
40	960581	22	M	YES	-	1	E2	-	-	2	1	Remission	1.73	49	16	1	21	30	2	2	2	3	92.76	30.99	11	2.34
41	96769	62	F	YES	-	8	E2	-	-	2	2	Remission	1.51	68	30	5	30	26	25	0	0	1	69.47	30.47	10.5	0.45
42	905058	56	F	-	YES	1	-	3,2,1	110	-	-	Remission	1.62	65	25	4	28	19	19	0	0	2	-	0.00	12.3	1.42
43	151076	59	M	YES	-	7	E2	-	-	2	1	Remission	1.72	61	22	2	21	32	17	2	1	3	-	0.00	10	6.45
44	854536	41	F	YES	-	4	E2	-	-	2	1	Remission	1.65	61	22	2	25.8	31	10	0	0	3	82.47	30.29	11	1.36
45	34725	51	M	YES	-	9	E3	-	-	2	1	Remission	1.65	75	27	4	27.5	32	24	2	2	4	123.6	45.40	11	2.34
46	59164	57	M	YES	-	17	E2	-	-	2	1	Remission	1.63	105	40	5	33	28	18	2	2	5	184.6	69.48	12	0.67

Sr. No	MRD	Albumin	FU Intermediate	Weight1	BMI1	MAC1	Hand Grip Strength 1	Triceps Skin Fold Thickness1	MIRT1	MUST1	Disease Activity 1	FU Final	Weight2	BMI2	MAC2	Hand Grip Strength 2	Triceps Skin Fold Thickness 2	MIRT2	MUST2	Disease Activity 2
1	1008011	3.7	-	61	22	28	42	8	0	0	Remission	-	63	23	28.8	42	9	0	0	Remission
2	971920	3.4	-	63.2	21	25	38	6	0	0	Remission	-	62	21	25	34	6	0	0	Remission
3	477324	4.1	-	65	20	26	55	4	1	1	Remission	-	68	21	27	48	5	0	0	Remission
4	295265	3.3	-	51	20	23	18	8	1	1	Remission	-	53.7	21.5	23	20	8	1	1	Remission
5	419757	3.6	-	55	19	23	32	10	2	2	Remission	-	55	20	23	30	8	1	1	Remission
6	752767	3.1	-	56.1	22	24	28	12	0	0	Remission	-	58	21	24	22	13	0	0	Remission
7	910286	2.8	-	61.5	18	26	42	2	2	2	Active	-	66	19	28	35	4	1	1	Remission
8	44987	4.3	-	67	27	26	31	20	0	0	Remission	-	68	28	29	32	22	0	0	Remission
9	678866	3.6	-	64	24	27.8	38	29	0	0	Remission	-	62	23	27	32	28	0	0	Remission
10	1022598	3.2	-	70	22	27	45	8	0	0	Remission	-	70	22	28.5	54	8	0	0	Remission
11	55667	3.7	-	65	25	30	28	32	0	0	Remission	-	66	25	29	27	28	0	0	Remission
12	1026008	3.8	-	76	27	28	49	10	0	0	Remission	-	75	27	31	41	12	0	0	Remission
13	83920	3.6	-	59	23	24	25	20	0	0	Remission	-	62	24	21	25	20	0	0	Remission
14	653618	3.6	-	71	25	29	34	12	0	0	Remission	-	72	25	29	38	13	0	0	Remission
15	823162	4.1	-	56	24	26	22	20	1	1	Remission	-	57	24	26	19	20	0	0	Remission
16	468117	4.3	-	93	30	32.6	51	20	0	0	Remission	-	91	29	32	50	20	0	0	Remission
17	674382	3.6	-	58	24	26	31	9	0	0	Active	-	56	24	27	32	9	0	0	Remission
18	89456	3.2	-	57	25	25	20	10	0	0	Active	-	55	24	25	23	10	0	0	Remission
19	365794	3.6	-	49	19	29	47	12	1	1	Remission	-	49	19	25	40	10	1	1	Active
20	1022777	3.4	-	43	20	21	20	8	0	0	Remission	-	44	21	23	24	8	0	0	Remission
21	1002592	3.8	-	65	21	26	40	11	0	0	Remission	-	69	23	26	40	12	0	0	Remission
22	978333	3.4	-	81.8	25	26	31	20	0	0	Remission	-	82	25	26	34	20	0	0	Remission
23	772061	3.7	-	69	29	28	38	14	0	0	Remission	-	68	28	27.2	30	14	0	0	Remission
24	89295	3.8	-	67	27	31.5	27	22	0	0	Remission	-	68	27.5	30	23	21	0	0	Remission
25	971320	2.9	-	56	24	24	26	17	0	0	Remission	-	59	26	24	20	19	0	0	Remission
26	862203	4.2	-	60	25	25.5	14	10	0	0	Remission	-	60	25	20	14	10	0	0	Remission
27	875884	2.9	-	56	25	28	19	10	0	0	Remission	-	55	25	25	16	9	0	0	Remission
28	994844	3.6	-	69	28	31.3	37	30	0	0	Remission	-	68	28	31.2	32	30	0	0	Remission
29	995283	2.9	-	51	19	26	20	8	1	1	Remission	-	52	20	26	20	8	1	1	Remission
30	939561	2.4	-	52	19	22	27	5	1	1	Active	-	50	18	22	20	4	2	2	Remission
31	70253	3.7	-	63	27	27.5	14	10	0	0	Remission	-	64	27	28.5	14	18	0	0	Remission
32	289798	2.5	-	53	18	24	35	10	2	2	Remission	-	55	19	24	28	10	1	1	Active
33	509873	3.3	-	76	28	26	33	10	0	0	Remission	-	75	27	26	34	10	0	0	Remission
34	1078233	3.5	-	86	29	31	48	12	0	0	Remission	-	88	30	33	59	14	0	0	Remission
35	26159	3.8	-	71	25	27.5	35	20	1	1	Remission	-	73	26	28	32	20	0	0	Remission
36	34147	3.2	-	54	23	26	18	10	0	0	Remission	-	53	23	26	19	10	0	0	Remission
37	964449	3.7	-	67	27	27.5	23	12	1	1	Remission	-	68	27	28	21	12	0	0	Remission
38	850831	3.8	-	113	38	34	30	14	0	0	Remission	-	108	36	33.2	33	12	1	1	Remission
39	675741	3.2	-	69	22	24.5	32	17	0	0	Remission	-	71	23	27.5	34	8	0	0	Remission
40	960581	2.9	-	48	16	21	30	2	2	2	Remission	-	50	17	23	52	2	2	2	Remission
41	96769	3.7	-	69.5	30	30	28	26	0	0	Remission	-	70	30	30	21	26	0	0	Remission
42	905058	3.5	-	70	26	28	19	19	0	0	Remission	-	70	32	28	19	18	0	0	Remission
43	151076	2.9	-	67.4	23	24	21	17	0	0	Remission	-	68	23	25.5	32	10	0	0	Remission
44	854536	3.4	-	62	23	26	28	10	1	2	Active	-	64	23	26	24	10	0	0	Remission
45	34725	3.6	-	77	28	28	31	24	0	0	Remission	-	77	28	28	30	24	0	0	Remission
46	59164	3.4	-	102	39	34	26	18	1	2	Active	-	104	39	34.5	25	20	0	0	Remission

Sr. No	MRD	Age	Sex	UC	CD	Disease Duration	Disease Extent UC	Montreal Class CD	CDAI	Total Mayo Score	Partial Mayo Score	Disease Activity At Baseline	Height	Weight	BMI	BMI	MAC	Hand Grip Strength	Triceps Skin Fold Thickness	MIRT	MUST	SASK IBD	Skeletal Muscle Area	SMI	Hb	CRP
47	742378	38	M	YES	-	13	E1	-	-	2	1	Remission	1.67	64	23	3	24.5	36	8	2	1	3	-	0.00	10	9.34
48	559456	42	F	YES	-	7	E2	-	-	2	1	Remission	1.6	62	26	4	23	26	21	3	2	4	-	0.00	11	8.45
49	776964	32	M	YES	-	2	E2	-	-	2	1	Remission	1.75	66	22	2	25	35	11	1	1	2	-	0.00	8.7	1.34
50	87278	65	F	-	YES	5	-	3,3,2	98	-	-	Remission	1.55	64	27	4	25.5	18	7	0	0	3	79.51	33.09	7.8	2.87
51	669042	45	M	-	YES	3	-	3,1,3	106	-	-	Remission	1.7	71	24	3	29	50	5	1	0	2	-	0.00	15.9	6.34
52	507674	29	M	YES	-	3	E2	-	-	2	1	Remission	1.73	64	21	2	26	64	7	1	0	3	135	45.11	11	9.23
53	519440	50	F	YES	-	13	E1	-	-	2	1	Remission	1.55	43	18	1	23	28	15	2	2	4	47.93	19.95	11.6	6.34
54	30449	59	F	YES	-	23	E2	-	-	2	1	Remission	1.62	82	31	5	31	22	22	2	1	3	107.6	41.00	11.1	14.55
55	411218	63	M	YES	-	6	E2	-	-	2	1	Remission	1.65	78	28	4	30	30	11	0	0	1	-	0.00	13.9	2.23
56	602372	25	M	YES	-	3	E2	-	-	2	1	Remission	1.74	53	18	1	22	41	2	2	2	3	-	0.00	11.5	7.85
57	907671	27	F	YES	-	9	E2	-	-	2	1	Remission	1.63	61	23	3	26	22	16	0	0	1	-	0.00	11.2	2.31
58	411787	60	M	-	YES	2	-	3,1,2	143	-	-	Remission	1.63	65	24	3	27	25	9	0	0	0	-	0.00	11.4	0.65
59	901575	26	M	Yes	-	6	E2	-	-	2	1	Remission	1.72	86	29	4	32	48	25	0	0	3	-	0.00	9	1.23
60	1079144	58	F	YES	-	2	E2	-	-	2	1	Remission	1.51	56	24	3	25.5	22	12	0	0	1	78.74	34.53	9.8	0.54
61	1025320	48	M	YES	-	2	E3	-	-	2	1	Remission	1.76	65	21	2	24	41	10	0	0	2	-	0.00	10	0.78
62	399663	19	F	YES	-	4	E2	-	-	2	1	Remission	1.59	59	24	3	26	32	22	0	0	1	-	0.00	10.9	0.83
63	751314	49	F	YES	-	2	E3	-	-	2	1	Remission	1.6	56	22	2	26.2	20	20	0	0	1	-	0.00	12.3	0.34
64	586134	20	F	-	YES	3	-	2,2,3	116	-	-	Remission	1.62	48	18	1	21.2	18	11	2	2	3	-	0.00	11.7	4.54
65	828151	61	F	-	YES	3	-	3,1,2	108	-	-	Remission	1.54	61	26	4	26	20	30	0	0	2	-	0.00	12.6	1.56
66	993124	18	F	YES	-	2	E3	-	-	2	1	Remission	1.55	53	20	2	24.5	20	11	0	0	1	75.06	31.24	11	1.43
67	936596	34	F	YES	-	5	E2	-	-	2	1	Remission	1.56	63	26	4	26	27	15	0	0	1	90.33	37.12	9.8	1.08
68	399304	56	M	YES	-	1	E2	-	-	2	1	Remission	1.65	71	26	4	27	40	12	0	0	1	124.9	45.88	12.2	0.65
69	837226	41	F	-	YES	8	-	2,3,2	116	-	-	Remission	1.55	54	23	3	26	25	18	0	0	2	87.97	36.62	9.8	1.23
70	972898	35	M	YES	-	6	E1	-	-	2	1	Remission	1.69	52	18	1	23.5	20	6	2	2	4	71.27	24.95	10	7.84
71	349846	32	F	YES	-	4	E2	-	-	2	1	Remission	1.65	74	27	4	33	21	32	0	0	3	114.5	42.06	11	1.23
72	672565	32	M	YES	-	9	E2	-	-	2	1	Remission	1.76	86	28	4	27	24	20	2	1	3	162.8	52.56	8.7	15.23
73	163446	41	F	YES	-	7	E2	-	-	2	1	Remission	1.46	77	36	5	29	27	28	3	2	2	89.45	41.96	9	7.64
74	325682	41	F	YES	-	23	E3	-	-	2	1	Remission	1.59	53	21	2	24	24	12.5	0	0	2	76.81	30.38	10	0.65
75	130751	55	F	YES	-	6	E2	-	-	2	1	Remission	1.62	60	23	3	27.5	18	24	0	0	1	102.7	39.13	9.8	0.34
76	984662	28	F	YES	-	3	E3	-	-	2	1	Remission	1.53	62	26	4	30	26	12	2	1	3	-	0.00	9.6	9.32
77	965442	40	F	YES	-	1	E2	-	-	2	1	Remission	1.56	65	27	4	25	26	30	2	1	3	98.19	40.35	8.7	7.83
78	673594	41	F	-	YES	2	-	3,2,1	110	-	-	Remission	1.55	65	27	4	27	27	22	0	0	1	95.86	39.90	13.2	1.32
79	422951	32	M	YES	-	3	E3	-	-	2	1	Remission	1.62	57	21	2	27	38	7	1	0	2	-	0.00	11.8	5.67
80	827436	34	M	YES	-	7	E1	-	-	2	1	Remission	1.72	66	22	2	28	40	24.5	2	1	3	109.3	36.95	11	7.34
81	959816	20	M	YES	-	2	E2	-	-	2	1	Remission	1.7	47	16	1	20	50	2	2	2	3	92.6	32.04	12.1	3.24
82	1036058	38	F	YES	-	9	E2	-	-	2	1	Remission	1.5	62	27	4	28	28	11	0	0	1	88.22	39.21	12.5	2.12
83	644495	52	M	YES	-	8	E2	-	-	2	1	Remission	1.62	86	33	5	27	27	6	2	1	2	114.4	43.59	12.8	29.5
84	858124	41	M	YES	-	11	E2	-	-	2	1	Remission	1.54	54	23	3	26	35	9	0	0	1	102.1	43.05	11	2.13
85	872228	25	M	YES	-	2	E2	-	-	2	1	Remission	1.82	55	17	1	21	45	7	2	2	3	111.4	33.63	10	1.43
86	606759	34	M	YES	-	9	E2	-	-	2	1	Remission	1.57	54	22	2	25	23	6	0	0	1	86.86	35.24	9	1.27
87	1043301	34	M	-	YES	8	-	2,2,1	130	-	-	Remission	1.82	58	18	1	25	30	10	2	2	4	94.02	28.38	10.8	1.72
88	1043419	30	F	YES	-	7	E1	-	-	2	1	Remission	1.64	60	22	2	25	23	12	0	0	2	98.81	36.74	11.6	0.51
89	230205	32	F	YES	-	14	E2	-	-	2	1	Remission	1.42	63	30	5	31	21	26	0	0	3	121.7	60.36	11.7	3.21
90	1034993	31	M	YES	-	2	E2	-	-	2	1	Remission	1.67	67	24	3	24	38	10	2	1	3	-	0.00	11	8.23
91	996404	47	F	YES	-	5	E2	-	-	2	1	Remission	1.54	57	24	3	24.5	19	8	2	1	4	-	0.00	11	7.44
92	103367	42	F	YES	-	5	E2	-	-	2	1	Remission	1.56	51	22	2	25	33	20	1	1	2	90.51	37.19	10.1	2.34

Sr. No	MRD	Albumin	FU Intermediate	Weight1	BMI1	MAC1	Hand Grip Strength 1	Triceps Skin Fold Thickness1	MIRT1	MUST1	Disease Activity 1	FU Final	Weight2	BMI2	MAC2	Hand Grip Strength 2	Triceps Skin Fold Thickness 2	MIRT2	MUST2	Disease Activity 2
47	742378	2.8	-	63	23	24	30	8	0	0	Remission	-	64	23	24.5	28	8	0	0	Remission
48	559456	2.7	-	67.6	28	30	20	21	0	0	Remission	-	66	26	30	21	24	0	0	Remission
49	776964	3	-	66	21	27	45	10	1	0	Remission	-	65	21	26	50	4	0	0	Remission
50	87278	3.7	-	61	25	25	12	7	2	1	Active	-	58	24	25	14	7	2	1	Active
51	669042	3.1	-	79	27	32	54	7	0	0	Remission	-	78	27	32.5	50	12	0	0	Remission
52	507674	3.2	-	70	23	27.7	70	8	0	0	Remission	-	65	21.7	26	62	7	1	1	Remission
53	519440	2.9	-	50	20	20	32	12	0	0	Remission	-	48	20	23	34	12	1	1	Remission
54	30449	3.4	-	82	31	31	27	22	0	0	Remission	-	83	32	31.5	22	22	0	0	Remission
55	411218	3.6	-	77	30	30	36	10	0	0	Remission	-	76	28	30	26	10	0	0	Remission
56	602372	3.1	-	53	17	22.5	38	2	2	2	Remission	-	53	17	21.5	32	10	2	2	Remission
57	907671	3.5	-	62	23	26.5	21	17	0	0	Remission	-	64	24	26.8	22	18	0	0	Remission
58	411787	3.8	-	67	25	26	29	9	0	0	Remission	-	70	26	26.5	20	10	0	0	Remission
59	901575	3.5	-	85	29	32	46	14	1	0	Active	-	81	27	32	46	14	2	1	Active
60	1079144	3.5	-	57	25	26.5	22	12	0	0	Remission	-	58	25	27	22	12	0	0	Remission
61	1025320	3.4	-	69	22	27	34	8	0	0	Remission	-	69	22	27	34	8	0	0	Remission
62	399663	4.2	-	56	22	25	22	19	0	0	Remission	-	58	23	23	18	19	0	0	Remission
63	751314	3.8	-	56	22	26	26	20	0	0	Remission	-	55	22	22	20	20	0	0	Remission
64	586134	3.1	-	52	20	22	20	12	1	0	Remission	-	55	21	24	23	14	0	0	Remission
65	828151	3.6	-	61	26	26	18	29	0	0	Remission	-	61	26	25	14	30	0	0	Remission
66	993124	3.1	-	52	21	24.5	19	11	0	0	Remission	-	52	21	22	20	12	0	0	Remission
67	936596	3.8	-	62	25	26.5	22	14	0	0	Remission	-	62	25	27	24	13	0	0	Remission
68	399304	3.4	-	69	25	24	31	10	0	0	Remission	-	69	25	23	30	11	0	0	Remission
69	837226	3.3	-	56	23	26	28	27	0	0	Remission	-	56	23	25	26	26	0	0	Remission
70	972898	2.6	-	54	19	23.8	27	6	1	1	Remission	-	56	20	24	26	7	1	1	Active
71	349846	3.2	-	75	27	33.3	22	32	1	0	Active	-	75	27	32	21	30	0	0	Remission
72	672565	3.1	-	86	28	26	24	21	0	0	Remission	-	84	27	25	23	20	0	0	Remission
73	163446	2.9	-	76	36	36	24	28	0	0	Remission	-	76	36	35	23	25	0	0	Active
74	325682	3.7	-	52	20	25	23	12	1	1	Remission	-	54	21	26	25	13	1	1	Remission
75	130751	3.4	-	61	23	27	20	24	0	0	Remission	-	59	22	26	21	22	0	0	Remission
76	984662	3.2	-	59	25	26	24	12	0	0	Remission	-	59	25	25	25	11	0	0	Remission
77	965442	3.1	-	63	25	25	29	20	0	0	Remission	-	61	24	25	28	19	0	0	Remission
78	673594	3.9	-	65	27	27	27	22	0	0	Remission	-	65	27	26	25	21	0	0	Remission
79	422951	3.2	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
80	827436	2.7	-	77	30	30	36	10	0	0	Remission	-	74	29	29	37	9	0	0	Remission
81	959816	2.9	-	46	16	21.5	50	1	2	2	Remission	-	46	16	21	48	2	2	2	Active
82	1036058	3.3	-	62.3	27	28	26	11	0	0	Remission	-	62	27	29	25	10	0	0	Remission
83	644495	3.1	-	86	33	29	32	6	0	0	Remission	-	83	32	28	30	7	0	0	Remission
84	858124	2.9	-	53	22	25	34	8	0	0	Remission	-	53	22	24	32	9	0	0	Remission
85	872228	2.8	-	60	18	25	40	6	2	2	Remission	-	63	19	24	42	7	2	2	Remission
86	606759	3.6	-	54	22	25	18	8	0	0	Remission	-	54	22	26	20	7	0	0	Remission
87	1043301	3	-	56	17	24	36	10	3	2	Active	-	58	18	23	35	11	2	2	Remission
88	1043419	3.8	-	61	23	25	30	14	0	0	Remission	-	61	23	24	29	15	0	0	Remission
89	230205	4.5	-	64	30	31	12	27	1	0	Active	-	62	29	29	13	26	0	0	Remission
90	1034993	2.9	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
91	996404	3.1	-	56	24	25.7	28	8	0	0	Remission	LFU	-	-	-	-	-	-	-	-
92	103367	3.3	-	80	33	30	20	20	0	0	Remission	LFU	-	-	-	-	-	-	-	-

Sr. No	MRD	Age	Sex	UC	CD	Disease Duration	Disease Extent UC	Montreal Class CD	CDAI	Total Mayo Score	Partial Mayo Score	Disease Activity At Baseline	Height	Weight	BMI	BMI	MAC	Hand Grip Strength	Triceps Skin Fold Thickness	MIRT	MUST	SASK IBD	Skeletal Muscle Area	SMI	Hb	CRP
93	971879	50	F	YES	-	1	E2	-	-	2	1	Remission	1.51	56	35	5	30	24	10	0	0	0	81.27	35.64	11	0.77
94	207763	26	F	YES	-	4	E1	-	-	2	1	Remission	1.61	52	20	2	24	19	16	0	0	1	73.52	28.36	9.8	0.23
95	293330	49	F	YES	-	4	E2	-	-	2	1	Remission	1.6	52	20	2	22	11	12	0	0	1	90.39	35.31	10	1.23
96	47310	28	F	-	YES	8	-	2,3,1	132	-	-	Remission	1.6	61	24	3	24	18	21	0	0	0	121.8	47.58	13.4	1.67
97	724672	29	M	YES	-	8	E2	-	-	2	1	Remission	1.73	89	30	5	35	30	14	3	2	3	151.7	50.69	14.1	14.62
98	1056135	42	M	YES	-	2	E2	-	-	2	1	Remission	1.76	73	23	3	25	45	12	0	0	1	126.4	40.81	14.3	1.23
99	1009906	25	M	YES	-	2	E2	-	-	2	1	Remission	1.77	75	24	3	25	56	20	4	3	5	154.3	49.25	11	24.27
100	172039	49	F	YES	-	11	E1	-	-	2	1	Remission	1.63	70	26	4	32	20	21	2	1	3	-	0.00	10	7.32
101	963149	18	F	YES	-	NEW	E2	-	-	8	6	Active	1.47	42	19	2	23	20	12	3	2	4	85.43	39.53	11.2	25.63
102	811145	47	M	YES	-	NEW	E2	-	-	8	6	Active	1.67	52	19	2	23.5	36	5	4	3	5	90.57	32.48	9.8	19.48
103	783808	51	M	YES	-	NEW	E2	-	-	5	3	Active	1.8	60	19	2	23	30	2	2	1	3	-	0.00	10.6	16.32
104	1058830	27	F	YES	-	NEW	E2	-	-	5	3	Active	1.56	41	17	1	21	24	7	4	3	5	130.6	53.67	11	28.32
105	1062508	57	F	YES	-	NEW	E2	-	-	5	3	Active	1.51	44	19	2	23	12	10	3	2	4	-	0.00	9	25.67
106	226508	48	F	YES	-	NEW	E2	-	-	9	5	Active	1.44	60	30	5	26	10	7	1	0	3	-	0.00	9.8	7.54
107	687369	18	M	YES	-	NEW	E2	-	-	8	6	Active	1.84	69	21	2	27.5	33	10	0	0	2	-	0.00	13.1	3.45
108	1080368	30	F	YES	-	NEW	E2	-	-	7	5	Active	1.57	40	16	1	21	20	4	2	2	4	-	0.00	13.3	2.13
109	1034454	30	M	YES	-	NEW	E2	-	-	9	7	Active	1.7	77	27	4	32	45	9	3	2	4	-	0.00	13.9	15.67
110	733160	62	F	YES	-	NEW	E2	-	-	6	4	Active	1.59	50	20	2	24	11	12	2	2	3	-	0.00	11	4.23
111	820332	51	F	-	YES	NEW	-	3,3,3	430	-	-	Active	1.54	66	28	4	29	21	26	2	1	3	93.68	39.50	13.4	15.97
112	972974	39	F	-	YES	NEW	-	2,2,1	286	-	-	Active	1.67	64	23	3	24	28	21	2	1	3	72.46	25.98	11.6	15.67
113	1005297	21	F	YES	-	NEW	E3	-	-	7	5	Active	1.55	51	21	2	26.5	26	26	0	0	3	83	34.55	12.5	3.25
114	714774	31	M	YES	-	NEW	E3	-	-	6	4	Active	1.76	78	25	4	29	45	19	0	0	2	-	0.00	12	2.34
115	1141268	27	M	YES	-	NEW	E2	-	-	9	7	Active	1.8	67	21	2	23	29	3	2	1	4	-	0.00	12	15.03
116	1034242	23	M	YES	-	NEW	E3	-	-	6	4	Active	1.71	52	18	1	21	26	3	3	3	3	-	0.00	8.1	3.22
117	1069711	63	M	-	YES	NEW	-	3,1,1	441	-	-	Active	1.67	55	20	2	21	24	4	7	4	6	99.5	35.68	7.1	67.3
118	1079254	55	M	YES	-	NEW	E2	-	-	9	7	Active	1.6	80	31	5	28	28	18	1	0	2	125.7	49.10	13.1	13.45
119	953932	29	F	YES	-	NEW	E2	-	-	5	4	Active	1.52	36	16	1	21	12	3	2	2	4	56.51	24.46	13.3	2.12
120	1007731	48	F	-	YES	NEW	-	3,3,2	163	-	-	Active	1.47	82	38	5	28	19	29	0	0	2	95.96	44.41	12	2.43
121	1113989	35	F	YES	-	NEW	E2	-	-	10	8	Active	1.51	48	21	2	24.5	22	8	1	0	3	89.09	39.07	11.3	9.23
122	931603	52	M	-	YES	NEW	-	3,2,1	350	-	-	Active	1.69	64	22	2	27.5	33	8	3	2	4	124.5	43.59	10.7	30.1
123	1134100	32	F	YES	-	NEW	E2	-	-	9	7	Active	1.5	45	20	2	23	19	18	2	2	4	93.77	41.68	9.9	4.56
124	1144985	45	M	YES	-	NEW	E3	-	-	8	6	Active	1.74	75	25	4	26	49	10	0	0	2	118.9	39.27	15.5	2.34
125	1040950	49	F	-	YES	NEW	-	2,2,1	290	-	-	Active	1.65	54	20	2	29	27	12	2	1	4	-	0.00	7.5	13.2

Sr. No	MRD	Albumin	FU Intermediate	Weight1	BMI1	MAC1	Hand Grip Strength 1	Triceps Skin Fold Thickness1	MIRT1	MUST1	Disease Activity 1	FU Final	Weight2	BMI2	MAC2	Hand Grip Strength 2	Triceps Skin Fold Thickness 2	MIRT2	MUST2	Disease Activity 2
93	971879	4.3	-	63	28	32.5	28	20	0	0	Remission	LFU	-	-	-	-	-	-	-	-
94	207763	3.6	-	52	20	25	22	16	1	1	Remission	LFU	-	-	-	-	-	-	-	-
95	293330	3.3	-	54	21	26.5	22	12	0	0	Remission	LFU	-	-	-	-	-	-	-	-
96	47310	3.6	-	65	25	27.5	16	16	0	0	Remission	LFU	-	-	-	-	-	-	-	-
97	724672	3.3	-	89	30	35	28	14	0	0	Active	LFU	-	-	-	-	-	-	-	-
98	1056135	3.2	-	79	25	26.5	41	10	0	0	Remission	LFU	-	-	-	-	-	-	-	-
99	1009906	3.5	-	79	25	26	44	10	0	0	Remission	LFU	-	-	-	-	-	-	-	-
100	172039	3.3	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
101	963149	3.2	-	42.6	17	25	22	12	2	2	Remission	-	42	19	24	16	12	1	1	Remission
102	811145	3.3	-	53	19	24.3	46	6	2	1	Active	-	54	19	23	33	4	1	1	Active
103	783808	3.1	-	62	19	24	40	2	1	1	Remission	-	62	19	24	38	2	1	1	Active
104	1058830	3.5	-	41	17	21	21	7	2	2	Remission	-	49	20	24.5	13	8	0	0	Remission
105	1062508	2.8	-	41	18	22	11	9	3	2	Active	-	46	20	22	10	9	0	0	Remission
106	226508	3.6	-	59	28	27.5	18	7	0	0	Remission	-	59	26	26	14	18	0	0	Remission
107	687369	3.7	-	72	21	26	25	10	0	0	Remission	-	82	24	31	42	12	0	0	Remission
108	1080368	3.1	-	41.8	17	21	28	4	2	2	Remission	-	46	19	23	26	10	1	1	Remission
109	1034454	3.2	-	75	26	30	30	10	0	0	Remission	-	80	28	33.8	46	4	0	0	Remission
110	733160	3.5	-	52	20	23.8	23	12	1	1	Remission	-	55	22	26	21	13	0	0	Remission
111	820332	2.9	-	66	28	29	21	26	1	0	Active	-	65	27	30	26	26	1	0	Active
112	972974	3.4	-	68	25	29	30	21	0	0	Remission	-	68	25	28.5	28	21	0	0	Remission
113	1005297	3.5	-	50	21	25.5	30	26	0	0	Remission	-	51	21	25.5	27	26	0	0	Remission
114	714774	2.9	-	77	25	28.5	50	20	1	0	Active	-	80	26	30	46	18	0	0	Remission
115	1141268	2.7	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
116	1034242	3.3	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
117	1069711	2.6	-	54.8	20	22.5	30	4	1	1	Remission	-	54	20	21	30	6	1	1	Active
118	1079254	3.1	-	86	33	31	35	19	0	0	Remission	-	86	33	30	34	18	0	0	Remission
119	953932	2.9	-	38	16	22	20	4	2	2	Remission	-	40	17	23	23	5	2	2	Active
120	1007731	4.4	-	83	38	29	20	29	0	0	Remission	-	82	38	28	19	27	0	0	Remission
121	1113989	3.2	-	49	21	24	30	9	0	0	Remission	-	49	21	23	29	10	0	0	Remission
122	931603	3.4	-	64	22	28	38	9	0	0	Remission	LFU	-	-	-	-	-	-	-	-
123	1134100	3.7	-	51	22	26.5	23	18	1	0	Active	LFU	-	-	-	-	-	-	-	-
124	1144985	3.9	-	81	27	32.8	50	10	0	0	Remission	LFU	-	-	-	-	-	-	-	-
125	1040950	3.2	LFU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-